NOTE: This portion of the document should not appear on produced Labels or IFUs. Stryker Instruments (269) 323-7700 (800) 253-3210	**Dimensions:** 8.5 inch (width) x 11 inch Booklet	**Color/Material/Finish:** Four Color Graphics on White Background; 20# Bond or Equivalent	**Label Stock:** N/A	
			Description/Type: Instructions For Use	
	Print Location: Print Center	**Suppliers/Services:** N/A	**Part Number:** 0406-900-702	**Rev.** E

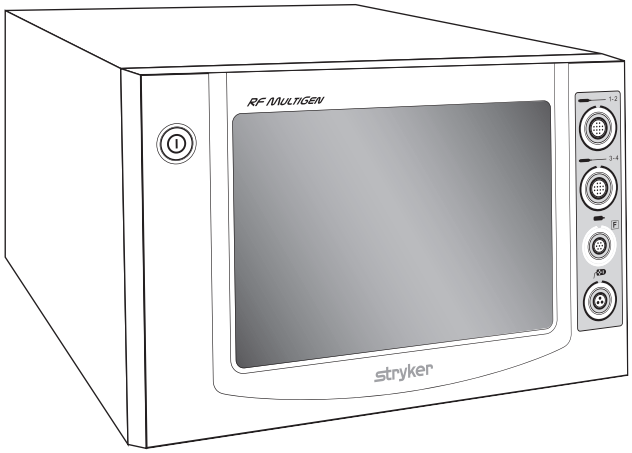
Interventional Spine (IVS)

RF MultiGen® Generator

REF 0406-900-000

Instructions For Use

R_x ONLY



Software Version

5.x

ENGLISH (EN)

Content

Content (continued)

Figures

Figures (continued)

Introduction

This *Instructions For Use* manual is the most comprehensive source of information for the safe and effective use of your product. This manual may be used by in-service trainers, physicians, nurses, surgical technologists, and biomedical equipment technicians.

Keep and consult this reference manual during the life of the product.

The following conventions are used in this manual:

- A **WARNING** highlights a safety-related issue. ALWAYS comply with this information to prevent patient and/or healthcare staff injury.
- A **CAUTION** highlights a product reliability issue. ALWAYS comply with this information to prevent product damage.
- A **NOTE** supplements and/or clarifies procedural information.

If additional information, especially safety information, or in-service training is required, contact your Stryker sales representative or call Stryker customer service.

User/Patient Safety

WARNINGS:

- Only trained and experienced healthcare professionals should use this equipment.
- Before using any system component or any component compatible with this system, read and understand the instructions. Pay special attention to WARNING information. Become familiar with the handling characteristics, the intended use(s) of this equipment, and system components prior to use. Contact your Stryker sales representative or customer service for in-service training.
- The healthcare professional performing any procedure is responsible for determining the appropriateness of this equipment and the specific technique for each patient. Stryker, as a manufacturer, DOES NOT recommend surgical procedure.
- Upon initial receipt and before each use, operate the equipment and inspect each component for damage. DO NOT use any component if damage is apparent. Only trained and experienced healthcare professionals should maintain this equipment. See the *Interventional Spine (IVS) Care Instructions*.
- DO NOT use this equipment in areas in which flammable anesthetics or flammable agents are mixed with air, oxygen or nitrous oxide.
- DO NOT use this equipment in the presence of endogenous gases.
- DO NOT use this equipment in the presence of cotton, wool or gauze that is saturated with oxygen.
- Take special precautions regarding electromagnetic compatibility (EMC) when using medical electrical equipment like this system. Install and place this system into service according to the EMC information contained in this manual. Portable and mobile RF communications equipment can affect the function of this system.
- DO NOT use this equipment with patients having a cardiac pacemaker or pacemaker electrodes unless otherwise directed by the cognizant cardiology department.

WARNINGS:

- Patients taking steroids and patients with pacemakers, lupus, gout, uncontrolled diabetes, Ehlers-Danlos syndrome, prior open capsular procedures, autoimmune disease, or etiologies where their immune systems are compromised require special consideration.
- To prevent a system failure that could delay surgery, DO NOT operate the generator outside of its prescribed environmental conditions. See the *Specifications* section.
- Wipe away any potentially flammable liquids underneath the patient or in body recesses or cavities before using the equipment.
- Apply dry gauze as required to avoid skin-to-skin contact between the patient's arms and body.
- DO NOT allow the patient to come in contact with metal parts that are grounded or have a large capacitance with respect to ground (operating table, supports). Use antistatic covers as required.
- When RF electro-surgical and physiological monitoring equipment are used simultaneously on the same patient, position the monitoring electrodes as far away from the surgical electrodes as possible, especially if no protective resistors or RF chokes are present. DO NOT use needle electrodes for monitoring.
- ALWAYS use patient monitoring systems that include high frequency current limiting devices. Failure to comply may cause the patient monitoring equipment to malfunction.
- DO NOT allow the leads to the surgical electrodes to touch the patient or other leads.
- Place temporarily unused electrodes connected to the generator in an electrically-insulated container. Never place an unused, connected electrode on the patient.
- ALWAYS use parallel bipolar techniques for surgical procedures where high frequency current could flow through parts of the body that have a relatively small cross sectional area. Failure to comply may cause undesirable tissue damage and result in patient injury.

Indications For Use

The Stryker RF MultiGen (generator), in combination with the Stryker RF Electrodes and Cannulae, are intended for coagulation of soft tissues in orthopedic, spinal, and neurosurgical applications. Examples include, but are not limited to: Facette Denervation, Trigeminus Neuralgia, Peripheral Neuralgia and Rhizotomy.

The Stryker MultiGen Cable is intended for coagulation of soft tissues in orthopedic, arthroscopic, spinal, and neurosurgical applications in combination with the separately cleared Stryker RF MultiGen, Electrodes and Cannulae. Examples of procedures include, but are not limited to, Facette Denervation, Trigeminus Neuralgia, and Rhizotomy.

Contraindications

None known.

Accessories

WARNINGS:

- Use only Stryker-approved system components and accessories, unless otherwise specified. Other system components and accessories may not properly fit into connectors or operate with the generator, and may result in increased emissions or decreased immunity of the generator.
- DO NOT modify any system component or accessory, including the ground connection of the power cord.

Specifically:

- Use only Stryker-approved cannulae.
- Use only Stryker-approved ground pads.
- Cannulae are SINGLE USE ONLY. DO NOT use if package is damaged. DO NOT reuse. DO NOT resterilize single use accessories.
- Ground pads are SINGLE USE ONLY. DO NOT reuse.
- DO NOT reuse, reprocess, or repackage a single use device. A single use device is intended for a single use only. A single use device may not withstand chemical, chemical vapor, or high temperature sterilization reprocessing. Design features may make cleaning difficult. Reuse may create a serious risk of contamination and may compromise the structural integrity of the device resulting in operational failure. Critical product information may be lost if the device is re-packaged. Failure to comply may lead to infection or cross-infection and result in patient and/or healthcare staff injury.

DESCRIPTION	REF
MultiGen Cable	0406-900-100
RF Hand Controller	0406-850-100
Cable Identification Tags	0406-900-200
Ground Pad (neutral electrode)	0406-650-205
Ground Pad Cable (monopolar return electrode cable)	0406-850-200
Sterile Plastic Bag	0406-001-000
Venom® Nitinol Electrodes	0406-825-01X series
Venom RF Cannulae	0406-XXX-XXX series
Additional Electrodes, Cannulae, and Catheters	See below.

NOTES:

- If you need more information, contact your Stryker sales representative for a complete list of accessories, including Stryker-approved electrodes, cannulae and catheters.
- See the instructions for use supplied with the Venom electrodes and cannulae for important safety and compatibility information.
- Stryker does not sell printers for the generator. As a minimum requirement, any printer used with the generator must be printer command language level 3 (PCL3) compatible. Printers using versions of PCL greater than 3 may also work. See your printer manual for compatibility information. Incompatible printers will not work with the generator.

System Overview (see figure 1)

The generator applies temperature-controlled, radio frequency (RF) energy to targeted nerve tissue using an active electrode. The generator is capable of supplying RF energy to a maximum of four electrodes concurrently using a timed-delivery method. Using monopolar electrode(s), parallel bipolar electrode(s), or NiTRODE™ coaxial bipolar electrode(s), the application of RF energy causes a thermal reaction in the body to create a lesion at the targeted site. The generator monitors impedance of the targeted site during lesion creation. Lesion creation inhibits the nerve tissue's ability to conduct electrical signals. Pain relief is achieved when these transmitted electrical signals are interrupted.

Key user interface features include the display, software, and remote operation.

The display, with its color, touch-sensitive screen, provides an intuitive graphical user interface that allows the operator to select settings and enter data.

The software has a modular structure that includes sensory stimulation, motor stimulation, lesion creation, and a procedure summary. To enhance usability and promote safety, these screens are color-coded. The system settings screens include registration, display, sound, date and time, language, and procedure defaults. These screens allow the operator to modify such settings as display brightness and speaker volume for audio output. The file/folder management screens allow the operator to create and modify folders and files that contain preferred procedures and settings. Up to 25 files may be stored electronically to improve efficiency. Patient information displayed on a procedure summary screen may be saved to a file or printed.

A RF Hand Controller may also be used to provide basic remote operation of the generator. See *Appendix A - RF Hand Controller Instructions* section.

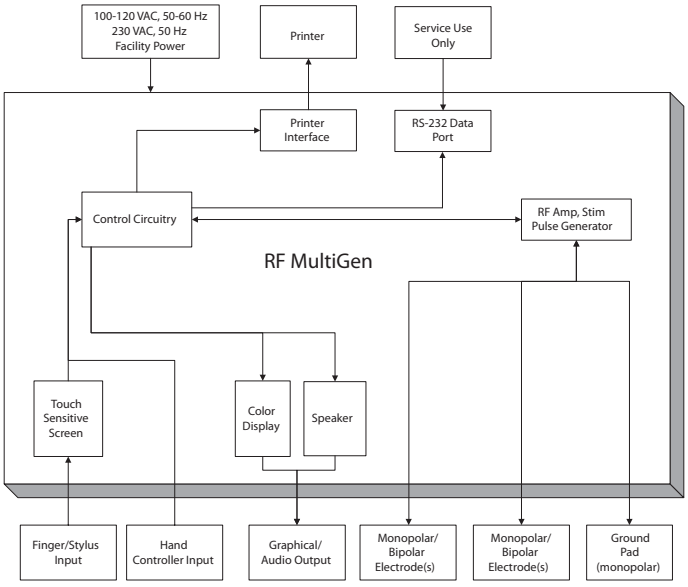


Figure 1 Block Diagram

NiTRODE is a trademark of the Stryker Corporation.

Procedural Overview

The patient's pain is localized using various diagnostic techniques. An assessment is made that RF treatment of the affected nerve tissue will improve the patient's symptoms. Reusable system components that will contact the sterile field are sterilized in advance of the procedure. The patient is positioned on a fluoroscopic imaging table and the surgical site is prepped using standard techniques. The system is turned on, and accessories are connected to the generator. To start a procedure, either a saved file is selected, or the system default settings are used. The desired cannula is placed in the target tissue region under fluoroscopic guidance. After the cannula has been placed in the general location, the electrode is inserted into the cannula.

Sensory stimulation and motor stimulation are used to facilitate the proper placement of the electrode/cannula before lesion creation. Targeting information is provided by monitoring tissue impedance and providing low frequency stimulating signals to obtain additional information. Sensory stimulation controls are used to control the nerve stimulator output and help position the active tip of the electrode/cannula next to the target nerve tissue. Motor stimulation controls are used to help the clinician rule out proximity of the electrode/cannula active tip to motor nerves. During this stimulation, impedance is displayed to assist the clinician in the proper placement of the electrode/cannula active tip.

The RF energy output (THERMAL/PULSE) screen is used to control the RF energy output to an active electrode tip. During output, targeted nerve tissue is exposed to RF energy. A temperature sensor built into the electrode tip measures the temperature in the surrounding tissue. The generator monitors temperature and adjusts RF energy based on the temperature readings. The generator monitors and displays various key parameters in real time continuously to help maximize safety and operating efficiency during all phases of the procedure. Temperature and impedance values are updated continuously and displayed on the generator screen. When the active electrode tip temperature reaches the set temperature value, the RF power output is reduced to prevent significant overshoot.

When a procedure is complete, the key parameter information used during the procedure may be viewed on a summary screen and printed.

A SET TEMPerature value and HOLD TIME (TIME) value are selected by the clinician. The set temperature value is not exceeded during either thermal or pulse modes.

In thermal mode, RF energy output is monitored and controlled by a hold time/set temperature feedback mechanism. An optimal temperature-rise rate is achieved and the desired set temperature value is maintained. The TIME value displayed begins to count down when the temperature value of the active electrode tip is within 2 degrees of the set temperature value. RF energy output is removed when the TIME value reaches zero. RF energy output may be removed at any time if the rate of temperature rise, the impedance, or the temperature value of the active electrode tip indicates a safety concern.

In pulse mode, the amplitude (voltage) of the RF energy pulses will be adjusted automatically to achieve the set temperature value of the active electrode tip while maintaining the set frequency and width. The TIME value begins to count down when the START button is touched and confirmed. When the TIME value reaches zero, the RF energy output is removed.

The pulse mode creates a significant electrical field to interact with the target nerve. This interaction is usually at a temperature value lower than the temperature necessary to cause cellular necrosis. Temperature rise is a by-product of the clinical application of RF energy. Therefore, the time required to reach the set temperature value during the pulse mode may be longer than during the thermal mode.

Features

Hardware Interface (see figure 2)

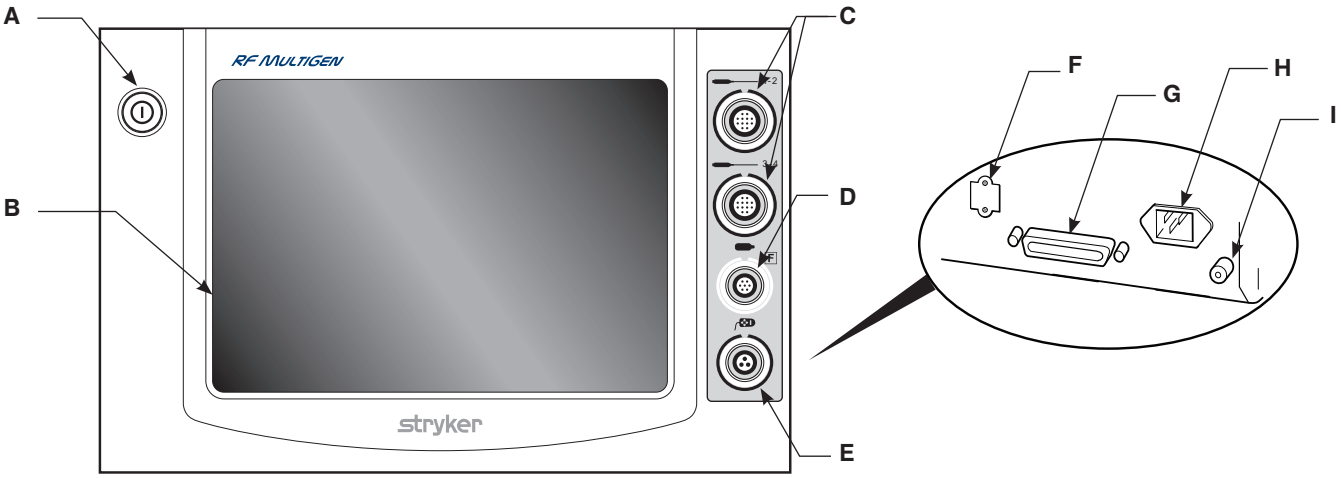


Figure 2 Hardware Interface

A	**ON/OFF Button** Press to apply power. Press to remove power.
B	**Color, Touch-sensitive Screen** Provides graphical user interface to select active electrodes and adjust setting values.
C	**Instrument Connector (two)** Allows installation of electrode.
D	**Ground Pad Connector** Allow installation of the ground pad cable.
E	**RF Hand Controller Connector** Allows installation of the RF Hand Controller.
F	**RS-232 Data Port (back panel)** Allows for software service updates installed by a Stryker-approved technician.
G	**Parallel Printer Cable Port (back panel)** Allows the installation of a PCL3 compliant printer.
H	**Power Receptacle (back panel)** Allows the installation of a power cord.
I	**Equipotential Grounding Lug (back panel)** Allows the installation a equipotential ground connection.

Symbol Definitions

The symbols located on the equipment and/or labeling are defined in this section or in the *Symbol Definition Chart*. See the *Symbol Definition Chart* supplied with the equipment.

SYMBOL	DEFINITION
1-2	Electrode(s) Port 1 (logical ports one and two)
3-4	Electrode(s) Port 2 (logical ports three and four)
	Ground Pad Port

SYMBOL	DEFINITION
	RF Hand Controller Port
	"ON" / "OFF" (push-push)
	General Warning Sign
	Alternating Current (AC)
	Type BF Applied Part
	Printer Cable Port (PCL3)
F	Floating Output
	Equipotentiality (equipotential ground)
	Refer to Instruction Manual/Booklet
	Fuse

System Components (see figure 3)

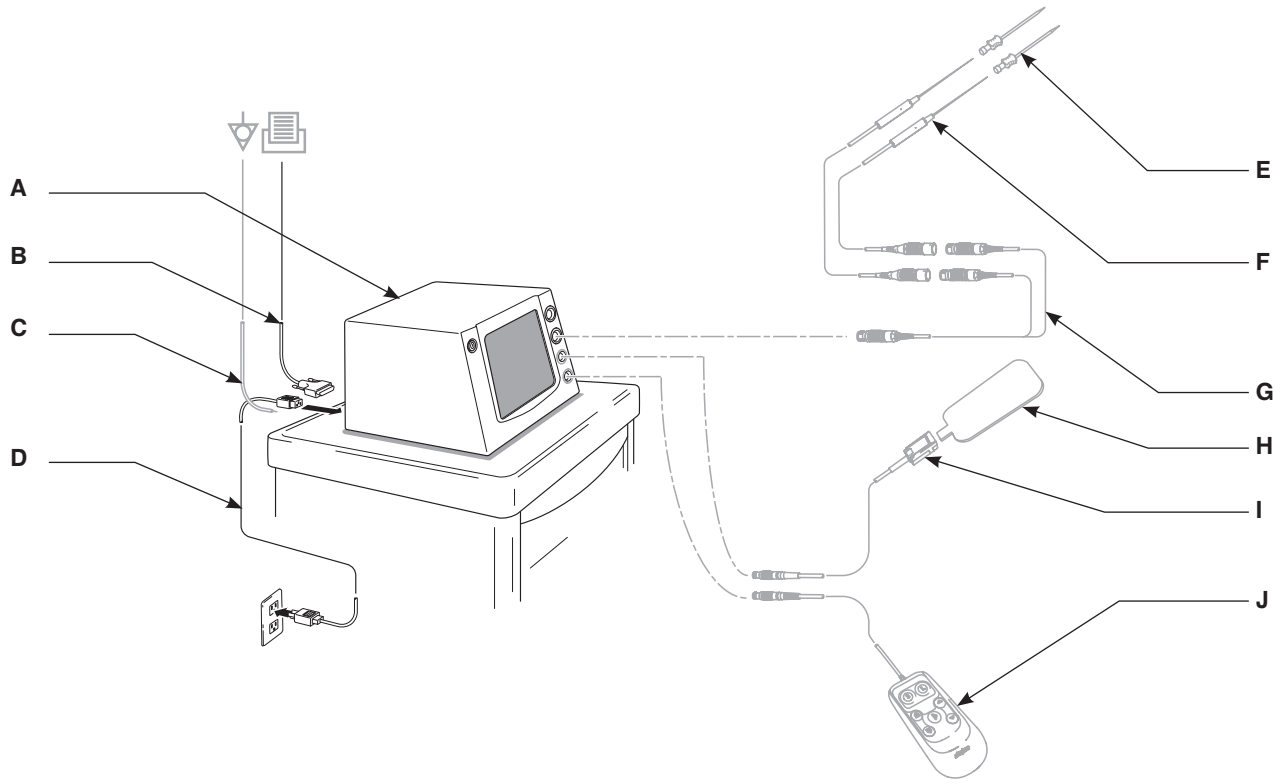


Figure 3 System Components

A	**RF MultiGen (generator)** Provides a controlled energy source for surgical purposes using a color-coded touch screen.
B	**Printer Cable** Provides the connection interface between the generator and a PCL3 compatible printer.
C	**Equipotential Grounding Cable** Provides the connection interface between the generator and a facility equipotential ground.
D	**Power Cord** Provides the connection interface between the generator and facility power.
E	**Monopolar Cannula** Provides targeted energy to the treatment site. (applied part)
F	**Monopolar Electrode** Delivers energy to the monopolar cannula and measures the temperature at the treatment site. (applied part)
G	**MultiGen Cable** Provides the connection interface between the generator and a maximum of two electrodes.
H	**Ground Pad (Neutral Electrode)** Used with monopolar electrode configurations only, the pad is placed securely on the patient's body in proximity to the site of the operation. (applied part)
I	**Ground Pad Cable (Monopolar Return Electrode Cable)** Provides the connection interface between the generator and the ground pad.
J	**RF Hand Controller** Provides basic remote control of the generator. See *Appendix A - RF Hand Controller Instructions* section.

NOTE: The designated applied parts as defined by the manufacturer. See the Product Safety Certification standards listed in the *Specifications* section.

Features

Screen Layout (see figure 4)

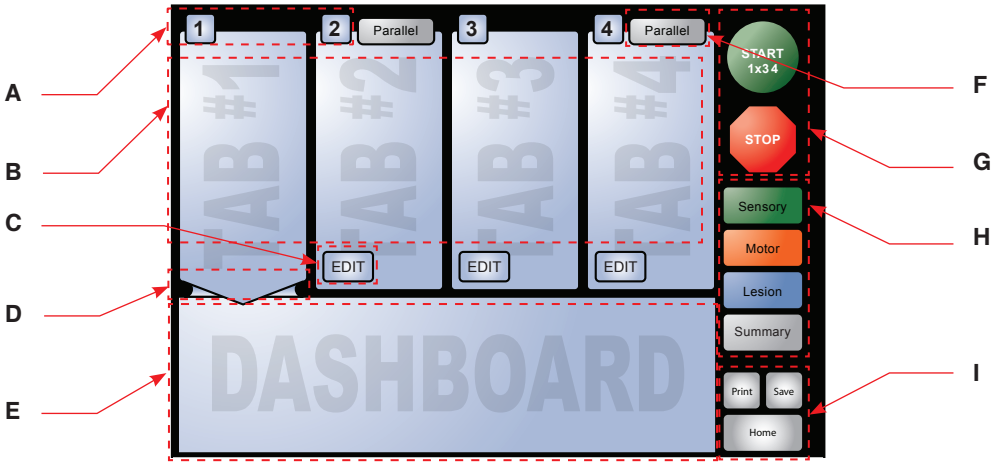


Figure 4 Screen Layout

A	**Electrode Identifier Numbers** The number corresponds to the electrode connected to the corresponding port. During the lesion mode, these identifier numbers become buttons that may be used to lock multiple procedure tabs. Locking multiple tabs and touching the START button will apply RF energy to each electrode simultaneously.
B	**Procedure Tab Area** Touch to select a tab that represents a connected electrode. The area will display electrode procedure information for the treatment site in real time.
C	**EDIT Button** Touch to access the dashboard area and edit specific electrode setting values.
D	**Bridge** When a procedure tab is selected, a connection or bridge is formed between the tab and the dashboard area.
E	**Dashboard Area** Displays the electrode information for the selected procedure tab. Access this color-coded area to edit the electrode setting values of the selected tab.
F	**PARALLEL Button** Touch to select the parallel bipolar mode to ON or OFF. When ON, two procedure tabs will merge (1,2) or (3,4). Two parallel bipolar stimulations cannot be performed at one time. Each parallel bipolar stimulation must be performed separately.
G	**START/STOP (ALL) Buttons Area** Touch to initiate or remove the application of RF energy. When RF energy is applied, the START button is gray. When RF energy is not applied, the STOP button is gray.
H	**Procedure Navigation Buttons Area** Touch to select sensory, motor, and lesion modes of operation. See *Modes of Operation and Color Codes* section. Touch the summary button to access procedural summary information. A visually depressed button indicates the current mode of operation.
I	**System Navigation Buttons Area** Touch to load and SAVE files, PRINT procedure information or access the HOME screen.

Modes of Operation and Color Codes

COLOR CODE	MODE
	Sensory Stimulation
	Motor Stimulation
	Lesion Creation/RF Output

Software Button Definitions

BUTTON	NAME	DEFINITIONS
	SELECTED ELECTRODE (INACTIVE)	Indicates the electrode has been selected and locked in lesion mode. Multiple electrodes may be selected and locked to apply energy concurrently or in a staggered manner.
	UNSELECTED ELECTRODE (INACTIVE)	Indicates the electrode is not selected and not locked. No energy is applied.
	ACTIVE ELECTRODE (NUMBER FLASHING)	Indicates the electrode is applying energy. During stimulation, only one procedure tab will indicate the application of energy.
	MERGED ELECTRODE TABS (ACTIVE)	Indicates tabs are merged and the electrodes are operating in the parallel bipolar mode. Energy will travel between the two electrode tips.
	CANCEL	Touch to exit a screen and return to the previous screen without saving changes.
	ENTER	Touch to apply a new or edited setting value.
	EDIT	Touch to edit an electrode setting value.
	DELETE	Touch to delete a file, folder, or setting value.
	START	Touch to apply energy to the assigned electrode(s). The numbers indicate the electrodes that will apply energy. Touch the START button in the dashboard area to apply energy.
	STOP (ALL)	Touch to remove energy from active electrode(s). During lesion creation ALL will appear on the button to indicate the use of more than one electrode.

BUTTON	NAME	DEFINITIONS
	SENSORY	Touch to access the sensory stimulation screen.
		Indicates the sensory stimulation screen is displayed.
	MOTOR	Touch to access the motor stimulation screen.
		Indicates the motor stimulation screen is displayed.
	LESION	Touch to access the RF Output screen.
		Indicates the RF Output screen is displayed.
	SUMMARY	Touch to access the procedure summary screen.
		Indicates the summary screen is displayed.
	HOME	Touch to access the home screen. A new procedure may be initiated from the home screen.
	PRINT	Only available from a procedure screen or a procedure summary screen, touch to print procedure summary information.
	SAVE	Touch to save the procedure file setting information.

Instructions (see figures 2 and 3)

To Perform Initial Setup:

WARNINGS:

- ALWAYS follow the recommended duty cycle to prevent the equipment from overheating. See the *Specifications* section.
- ALWAYS operate the equipment within the specified environmental condition values. See the *Specifications* section.

NOTE: To check the accuracy of the generator's displayed values including temperature, impedance and power output, see the *To Perform Check-in Procedure* section. These procedures may be performed in addition to any existing facility check-in protocol.

1. Place the generator on a flat, sturdy surface.
2. Connect one end of the equipotential bonding cable to the equipotential grounding lug on the generator and the other end to the facility grounding busbar (optional).

WARNING: To avoid the risk of electric shock, ALWAYS connect this equipment to a hospital-grade, facility power receptacle with protective earth.

NOTE: The universal power supply will automatically adjust to accommodate the voltage and frequency of facility power.

3. Connect the power cord between the power receptacle on the generator and a hospital-grade facility power receptacle with protective earth.
4. Press the ON/OFF button to apply power to the generator.

NOTE: When power is applied, the generator performs a self-diagnostics test to verify internal components, software, and connected components are working correctly. If the generator and components are operating correctly, the HOME screen will appear. If any fault occurs, an error message will appear on the display. As components are connected, additional testing occurs. If the generator does not power up, see the *Troubleshooting* section.

To Connect Electrode Cable(s):

WARNINGS:

- If using multiple electrodes, verify each cable tag number on the electrode matches the number on the port of the generator. Incorrectly matched cable and port numbers will misdirect applied RF energy. See *To Attach Cable Identification Tags* section before proceeding.
- DO NOT connect a MultiGen cable in series with another MultiGen cable.

CAUTIONS:

- When connecting or disconnecting any of the two types of cables to the front of the generator, always hold the cable by its connector (the plug, not the cord). The locking sleeve is the ridged portion of the connector. During removal, this ridged portion should be pinched and pulled straight back.
- Cables that are connected to the front of the generator have keyed, push-pull type connectors that lock into place. DO NOT attempt to force a connector into a generator port. Each connector and port has an alignment dot to indicate proper cable orientation.

NOTE: See the *Procedure Configurations Table* to select the appropriate connection configuration. See the instructions associated with the selected connection configuration.

1. Align the dot on the black end of the cable with the dot on the generator port and connect the cable to the generator.
2. Use the electrode port symbol as reference and match the color-coded black band on the port with the black cable strain relief.

To Attach Cable Identification Tags:

WARNING: During multiple electrode use, verify each number on the tag of an electrode matches and corresponds to the number on the port of the generator. Incorrectly matched cable and port numbers will misdirect applied RF energy.

NOTES:

- The cable identification tag number provides a matched link between the tagged physical electrode and the electrode identifier number on the display.
- If the tags require sterilization, the tags may remain on the cable during sterilization. See the *IVS Care Instructions*.
- The tags may be connected to the electrode cable and the MultiGen cable.
- When connecting a MultiGen cable to the generator, verify the cable tag numbers match the numbers on the port of the generator.
- When connecting an electrode cable to the MultiGen cable, verify the cable tag numbers on the electrode cable match the cable tag numbers on the MultiGen cable.

1. Slide the cable loop over and onto the cable. See figure 5 for suggested placement locations of the tags.
2. Snap the numbered base onto the cable loop. The numbered base should rotate freely on the loop.
3. To remove the numbered base, squeeze the cable loop and pull down on the numbered base. A new numbered base may be attached to the cable loop.

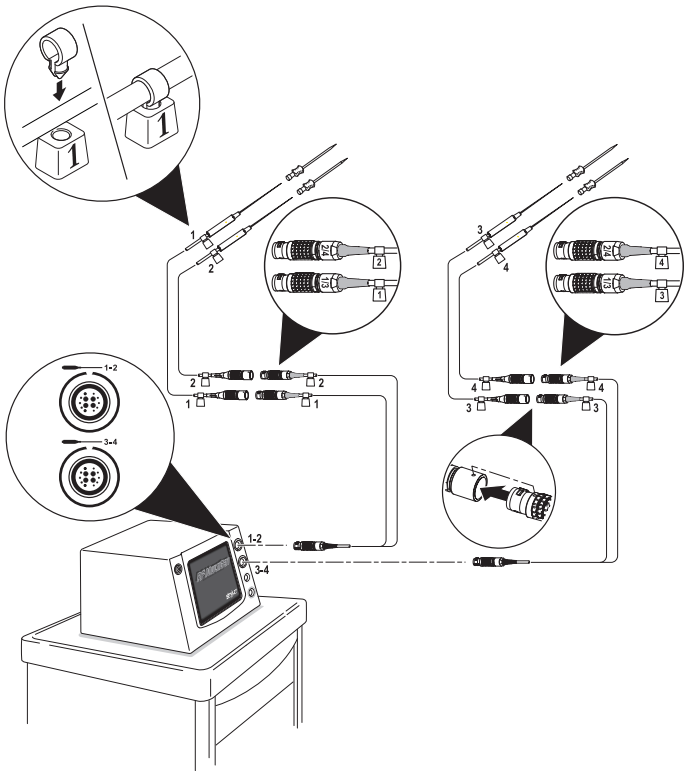


Figure 5 Cable Identification Tags

To Connect a Ground Pad (monopolar only):

1. Plug the generator end of the ground pad cable into the designated port on the generator. Use the ground pad port symbol as reference and match the white band on the port to the white cable strain relief.
2. Raise the connector latch at the other end of the cable, insert the ground pad tabs into the connector and close the latch to secure the ground pad.

WARNINGS:

- Place the ground pad with its entire surface securely on the patient's body in proximity to the treatment site.
- Properly affix the ground pad to the patient. Alcohol may be used to clean the site and eliminate poor adhesion caused by a wet surface or the use of lotion. Verify proper contact exists between the patient and the ground pad whenever the patient is repositioned after the initial application of the ground pad.
- ALWAYS make sure a safe contact exists between the ground pad and the patient. An auditory alarm will not occur if safe contact between the ground pad (neutral electrode) and the patient is not established or maintained.
- Properly locate and orient the ground pad on the patient to control the size and shape of the lesion during its creation.

NOTE: ALWAYS use and properly connect a ground pad to the generator for monopolar electrode configurations. The generator will not energize the monopolar electrode if a ground pad is not adequately connected and applied to the patient. If a ground pad is not connected or the connection is interrupted, an error message will appear on the display.

3. Place the pad portion of the ground pad onto the patient, in proximity to the treatment site (see figure 6). The entire pad should adhere to the patient's body.

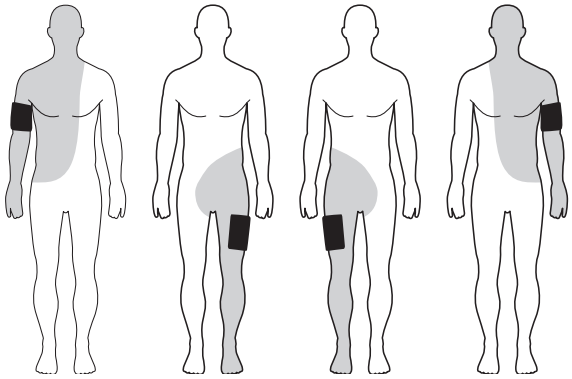


Figure 6 Pad Placement

To Connect a Printer (optional):

NOTE: As a minimum requirement, any printer used with the generator must be PCL3 compatible. Printers using versions of PCL greater than 3 may also work.

1. If using a printer, connect the printer cable to the parallel printer cable port on the generator and the appropriate printer receptacle.
2. Connect facility power to the printer.

To Connect a RF Hand Controller (optional):

1. If a RF Hand Controller is used (see Appendix A - *RF Hand Controller Instructions* section), align the dot on the cable connector end with the dot on the generator port and connect the cable to the generator.
2. Use the RF Hand Controller port symbol as a reference and match the color-coded gray band on the port with the gray cable strain relief to ensure the installation is correct.

Instructions (continued)

To Select a Procedure Configuration:

Procedure Configurations Table

NOTES:

- The multi-lesion capability allows the generator to lesion tissue using multiple electrodes. The RF energy is provided in short bursts that are timed to allow all the electrodes to heat at the same time. RF energy and voltages for stimulation are never supplied concurrently. Voltages used for stimulation may only be applied to one electrode at a time.
- RF energy is delivered through two electrode connector ports, each of which is segmented into two logical ports providing a total of four logical ports. The generator can support several combinations of electrode configurations. These combinations may be mixed between the two electrode connector ports.
- DO NOT use configurations other than those described below. Failure to comply will result in a system error.

PROCEDURE TYPE	NUMBER OF ELECTRODE(S)	GENERATOR CONNECTOR 1-2	GENERATOR CONNECTOR 3-4	GROUND PAD CONNECTOR	FIGURE NUMBER
Monopolar Procedure Configurations: capability allows the generator to create a lesion using a monopolar electrode with a ground pad.					
Single Monopolar	1	MultiGen Cable (0406-900-100)	Empty	Ground Pad Cable (0406-850-200)	7
		Empty	MultiGen Cable (0406-900-100)		
Two Concurrent Monopolar	2	MultiGen Cable (0406-900-100)	Empty	Ground Pad Cable (0406-850-200)	7
		Empty	MultiGen Cable (0406-900-100)		
Three Concurrent Monopolar	3	MultiGen Cable (0406-900-100)	MultiGen Cable (0406-900-100)	Ground Pad Cable (0406-850-200)	7 and 8
		MultiGen Cable 0406-900-100)	MultiGen Cable (0406-900-100)		
Four Concurrent Single Monopolar	4	MultiGen Cable (0406-900-100)	MultiGen Cable (0406-900-100)	Ground Pad Cable (0406-850-200)	7
Parallel Bipolar Procedures Configurations: capability allows the generator to create a lesion using two monopolar electrodes. The generator monitors the temperatures of both electrodes and controls the higher of the two electrode temperatures. Both temperatures are displayed on the screen.					
Single Parallel Bipolar	2	MultiGen Cable (0406-900-100)	Empty	Empty	9
		Empty	MultiGen Cable (0406-900-100)		
Two Concurrent Bipolar	4	MultiGen Cable (0406-900-100)	MultiGen Cable (0406-900-100)	Empty	
Monopolar and Parallel Bipolar Combination Procedure Configurations					
Monopolar and a Parallel Bipolar	3	MultiGen Cable (0406-900-100)	MultiGen Cable (0406-900-100)	Ground Pad Cable (0406-850-200)	7 and 9
		MultiGen Cable (0406-900-100)	MultiGen Cable (0406-900-100)		
Two Concurrent Monopolar and a Parallel Bipolar	4	MultiGen Cable (0406-900-100)	MultiGen Cable (0406-900-100)	Ground Pad Cable (0406-850-200)	7

To Configure a Monopolar Procedure or a Parallel Bipolar Combination Procedure Using MultiGen Cable(s)

1. See *To Perform Initial Setup* section.
2. See *To Connect Electrode Cable(s)* section.
3. See *To Attach Cable Identification Tags* section.
4. See *To Connect a Ground Pad (monopolar only)* section.
5. See *To Connect a Printer (optional)* section.
6. See *To Connect a RF Hand Controller (optional)* section.

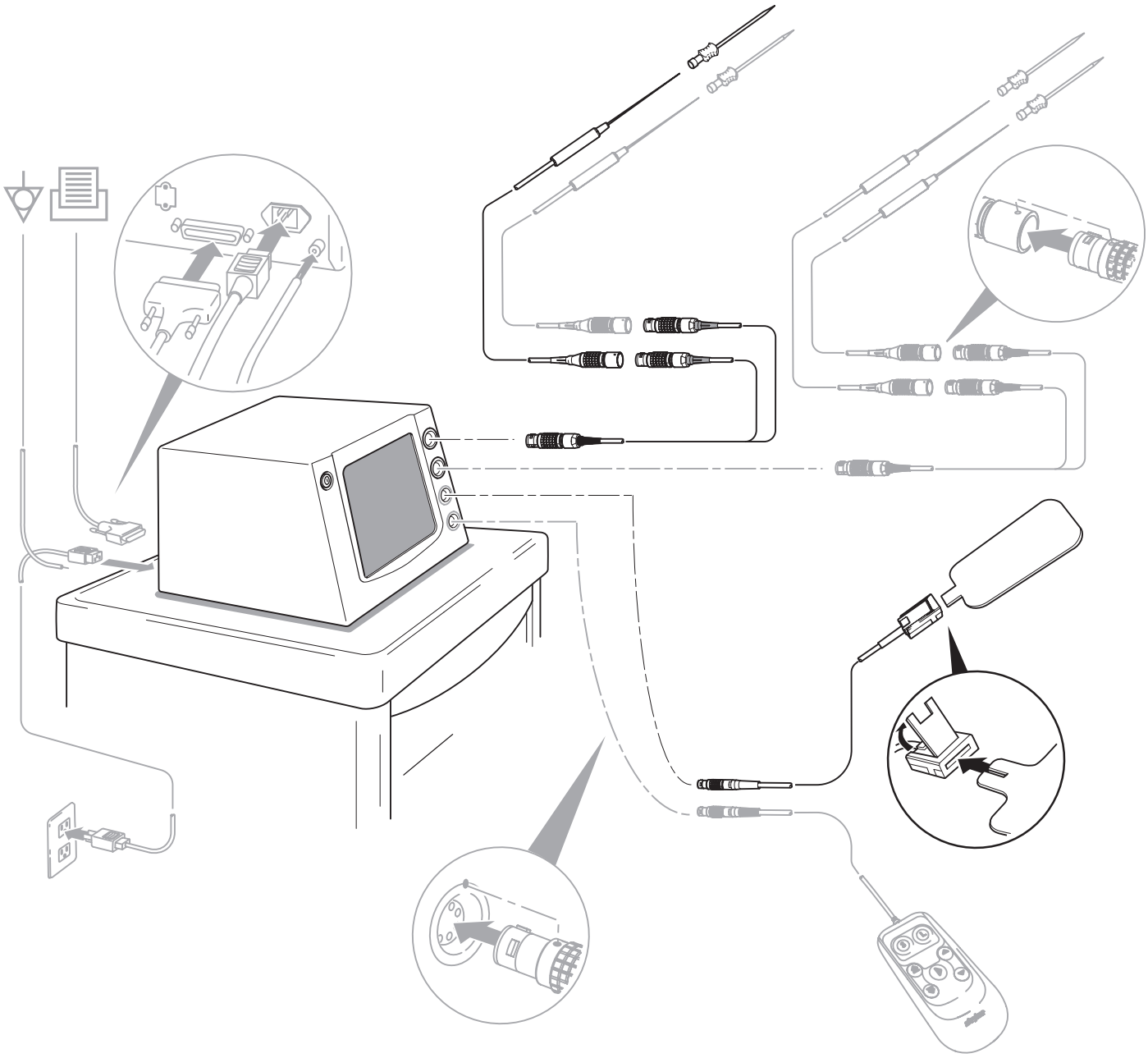


Figure 7 Monopolar or Monopolar and Parallel Bipolar Configuration

Instructions (continued)

To Configure a Parallel Bipolar Combination Procedure Using a MultiGen Cable

NOTE: The MultiGen Cable may be connected to either generator port.

1. See *To Perform Initial Setup* section.
2. See *To Connect Electrode Cable(s)* section.
3. See *To Attach Cable Identification Tags* section.
4. See *To Connect a Ground Pad (monopolar only)* section.
5. See *To Connect a Printer (optional)* section.
6. See *To Connect a RF Hand Controller (optional)* section.

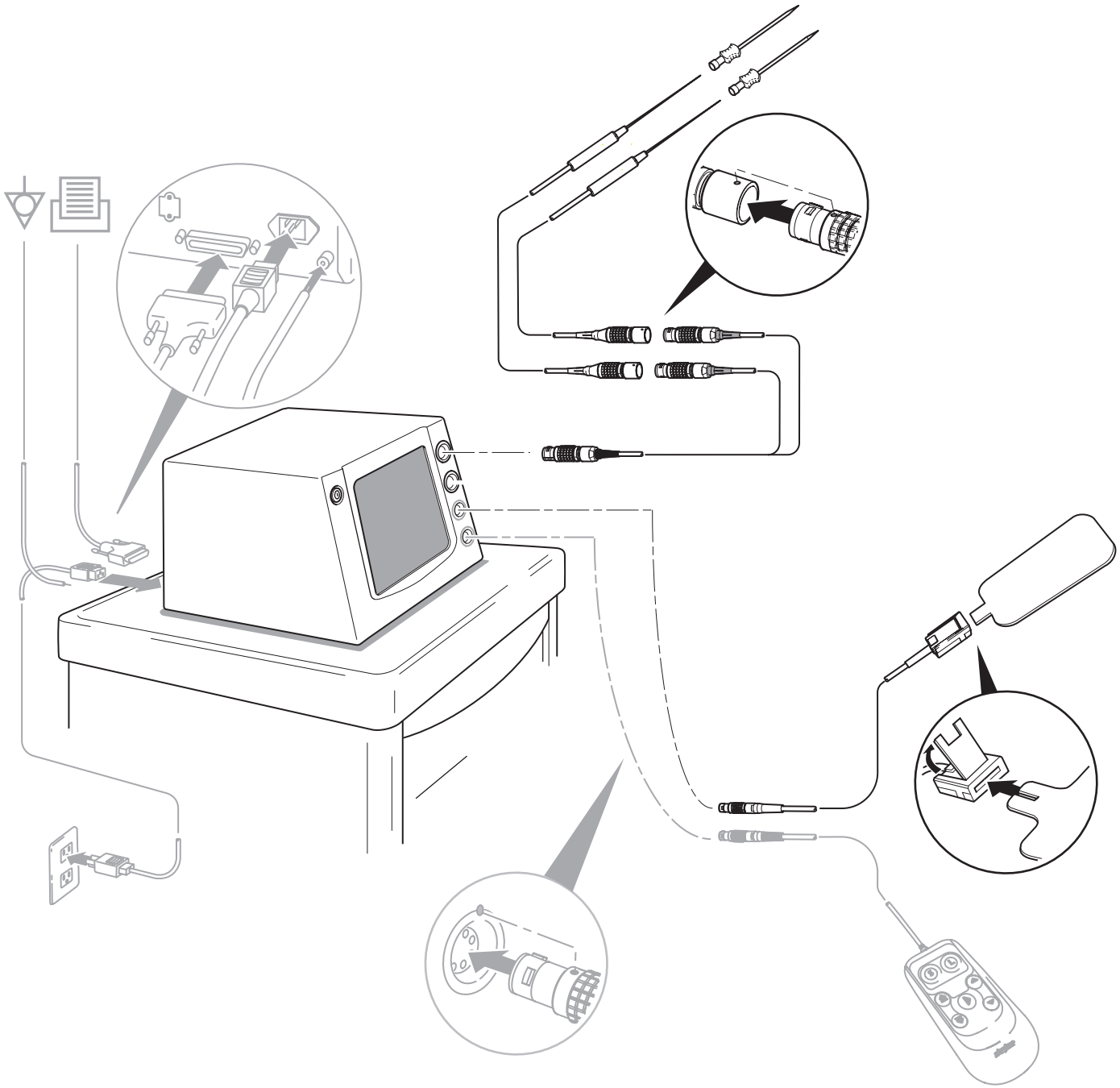


Figure 8 Monopolar or Monopolar and Parallel Bipolar Combination Configuration

To Configure a Parallel Bipolar Procedure Using MultiGen Cable(s)

1. See *To Perform Initial Setup* section.
2. See *To Connect Electrode Cable(s)* section.
3. See *To Attach Cable Identification Tags* section.
4. See *To Connect a Printer (optional)* section.
5. See *To Connect a RF Hand Controller (optional)* section.

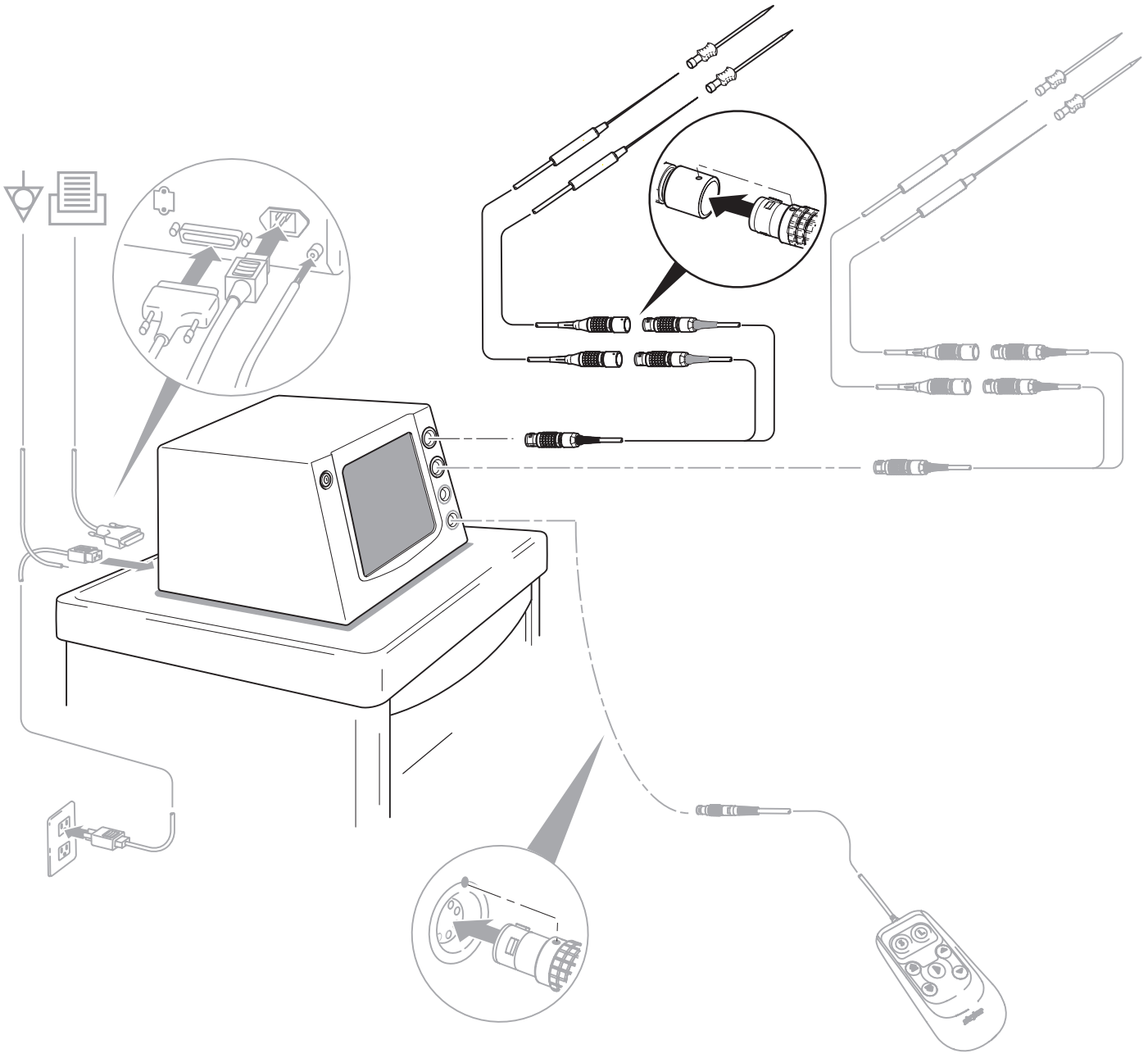


Figure 9 Parallel Bipolar Configuration

Instructions (continued)

To Start A Procedure

WARNINGS:

- Ensure the length of the electrode and cannula match by verifying the electrode color and cannula hub color are the same.
- Fully insert the electrode into the cannula to ensure the electrode tip is at the end of the cannula. Failure to comply may prevent proper temperature control.
- DO NOT reuse single use cannulae.
- DO NOT position the cannula tip in a blood vessel or bone. Failure to comply will cause the formation of a blood clot and may result in temperature overshoot.
- If using multiple electrodes, ensure the electrode identifier number on the procedure tab indicating the impedance value corresponds to the number of the cable identification tag on the electrode placed in the treatment site.
- DO NOT place multiple electrodes/cannulae close together to create a single large lesion when using a monopolar configuration. ALWAYS use one electrode/cannula to create one lesion. Failure to comply may cause temperature overshoot errors or a lesion with an unpredictable size and shape.
- When inserted, ALWAYS ensure the portion of the cannula's distal tip that is not insulated is NOT visible above the surface of the skin.

1. To start a procedure, touch the USE DEFAULT SETTINGS button to use system procedure values or the SELECT SAVED PROCEDURE button to use saved procedure values (see figure 10). If the USE DEFAULT SETTINGS button is selected, see *To Change System Settings: Procedure Default Settings* section if required. If the SELECT SAVED PROCEDURE button is selected, see *To Save or Access Saved Procedure Settings* section to create, edit, or select a folder/file for a procedure.
2. Under the guidance of X-ray or fluoroscopic technology, place the cannula tip in the target nerve tissue area.

NOTE: Fluoroscopic dye may be injected to facilitate the correct placement of the electrode/cannula tip in proximity to the target nerve tissue.

3. Remove the stylet from the cannula.
4. Place the electrode into the cannula and ensure its full insertion. Verify the impedance value displayed for the placed electrode/cannula is in the normal range.
5. If performing sensory or motor stimulation, ensure the frequency, width, and initial amplitude setting values have been adjusted as required. See *To Edit Sensory or Motor Stimulation Settings* section. Otherwise, see *To Perform Sensory or Motor Stimulation* section.

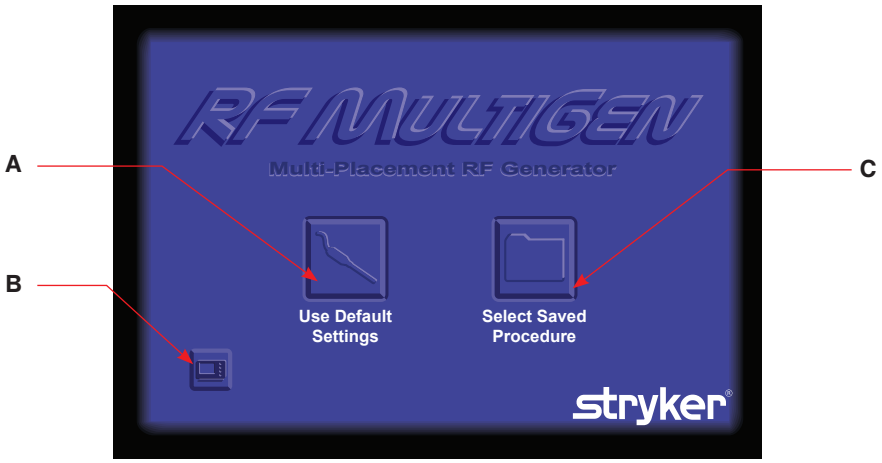


Figure 10 Home Screen

A	**USE DEFAULT SETTINGS Button** Touch to begin a procedure using the system (generator) procedure default settings file. These settings may be the original factory default settings or modified settings.
B	**SYSTEM SETTINGS Button** Touch to access the SYSTEM SETTINGS screen. From this screen, edit the system default settings, including registration information, display, sound, date and time, and language settings. The system procedure default settings may also be edited.
C	**SELECT SAVED PROCEDURE Button** Touch to access the SELECT FOLDER screen to create or edit a procedure settings file. Create or edit up to five folders with five files in each folder. From the FILE SETTINGS screen, touch the ACCEPT button to start the procedure.

To EDIT Sensory or Motor Stimulation Settings

NOTE: The sensory and motor stimulation screens have a similar look, feel and functionality (see figures 11 and 12). The values associated with each stimulation mode differ, but the setting types are the same. Only the sensory stimulation screens will be illustrated to explain how to edit stimulation setting values.

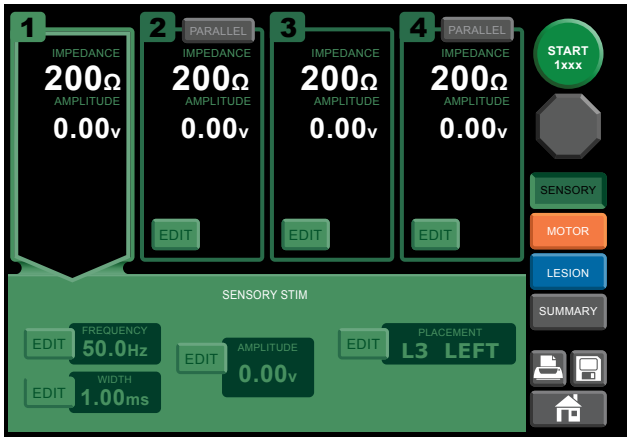


Figure 11 Typical Stimulation Sensory Screen - INACTIVE

Figure 12 Typical Stimulation Motor Screen - INACTIVE

Instructions (continued)

To EDIT Sensory or Motor Stimulation Settings (continued)

1. Touch the EDIT button in the procedure tab area to access the electrode setting values (see figure 13).
2. Adjust the frequency, width, and amplitude setting values by touching the corresponding EDIT button in the dashboard area (see figures 14 and 15). Electrode placement information may also be entered. See *To Choose a Placement Region* section.

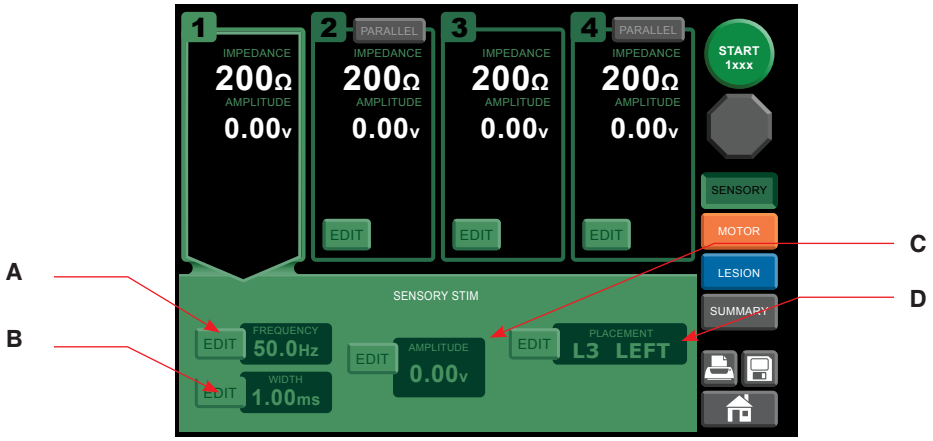


Figure 13 Typical Stimulation Screen - INACTIVE

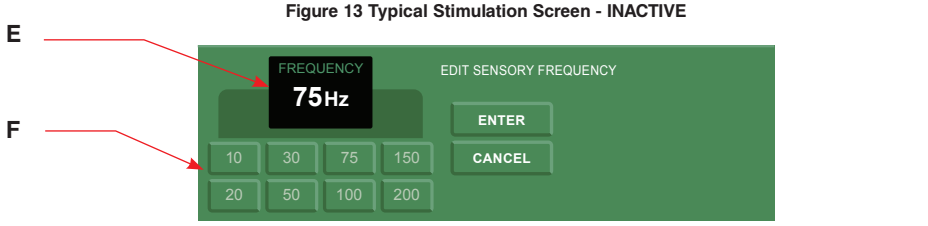


Figure 14 Typical Stimulation Preset Dashboard [FREQUENCY]

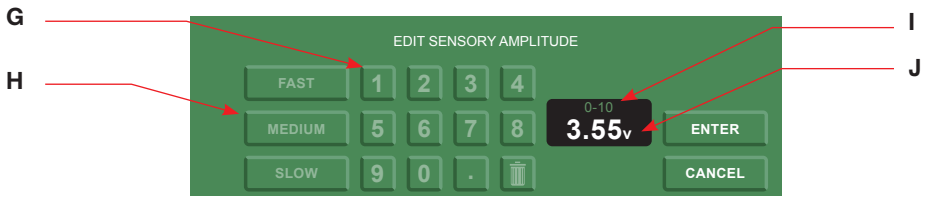


Figure 15 Typical Stimulation Keypad Dashboard [AMPLITUDE]

A	**EDIT FREQUENCY Button/Window** Touch to select a preset frequency. Once selected, the value is displayed in the window. This setting is not adjustable after the START button is touched.
B	**EDIT WIDTH Button/Window** Touch to select a preset width. Once selected, the value is displayed in the window. This setting is not adjustable after the START button is touched.
C	**EDIT AMPLITUDE Button/Window** Touch to enter a specific amplitude setting value. Once entered, the value is displayed in the window. This value is adjustable after the START button is touched.
D	**EDIT PLACEMENT Button/Window** Touch to select the electrode placement information. A dashboard will appear to allow the selection of the anatomical location of each electrode placement. Once selected, the anatomical location is displayed in the window. This information cannot be modified after the START button is touched. See *To Choose a Placement Region* section.
E	**Preset Value Window** Displays the value selected from one of the preset buttons.
F	**Preset Buttons** Touch to select a preset value.
G	**Keypad Buttons** Touch to enter a specific value. The value appears in the NEW VALUE window.
H	**STEP RATE** Touch the FAST, MEDIUM, or SLOW button to select a specific step rate for the amplitude adjustment value. The rate represents the steps per second the value will change when the amplitude adjustment arrow button on a procedure screen is touched.
I	**RANGE Area** View the acceptable range of values that may be entered for this setting.
J	**NEW VALUE Window** Displays the value entered using the keypad buttons.

To Perform Sensory or Motor Stimulation

NOTES:

- For safety purposes, the stimulation energy output is limited to 20 mA in the voltage-regulated mode.
- Only one electrode may provide an active stimulation energy output.
- Stimulation energy output consists of biphasic square pulses. The values displayed on the screen are peak-amplitude values and the width values for each phase. See *Appendix B - Maximum Frequency and Maximum Stimulation Width Graphs* section.
- If the amplitude value is 0.00 V, stimulation output will not start until the amplitude value is increased using the amplitude arrow buttons.
- The initial amplitude value will determine the stimulation energy output when the START button is touched. The initial amplitude value should be set slightly below the point at which clinical experience shows patient response may be perceived.
- Adjusting the amplitude value may reduce the time required to reach a value resulting in a patient response.
- For sensory stimulation, the amplitude value where the desired nerve is triggered will indicate how close the nerve is to the active electrode tip. Patient response at a lower amplitude value will indicate closer proximity to the target nerve.
- For motor stimulation, the amplitude value where the nerves are triggered will indicate how close the nerves are to the active electrode tip. Patient response at a lower amplitude value will indicate closer proximity to the triggered nerves. Patient response at too low a motor stimulation amplitude value increases the likelihood of damage to a motor nerve.
- If the patient is not responding: (1) reposition the electrode, and (2) verify the proper selection of frequency and width values.
- If the patient is responding at too low an amplitude value (indicating an undesired proximity to a motor nerve): (1) reposition the electrode and (2) verify the proper selection of frequency and width values.
- If using a fixed amplitude value, increasing the width value will pass more stimulation energy into the patient per pulse. In general, increasing the width value has the effect of recruiting more nerve fibers within the electrode's proximity and provoking a stronger response. Conversely, a reduction in the width value will reduce the patient's response.

1. Ensure the frequency, width, initial amplitude, and amplitude step rate values have been set as required. See *To EDIT Sensory or Motor Stimulation Settings* section.
2. If performing a parallel bipolar procedure, touch the PARALLEL button (see figure 16).
3. Touch the START button to apply stimulation energy using the setting values displayed in the procedure tab area. The active electrode identifier number will flash and an audible beep will sound to indicate the stimulation energy is applied (see figure 17).
4. Touch the FAST or SLOW amplitude arrow buttons to adjust the amplitude value of the stimulation output.
5. Touch the STOP button to remove stimulation energy output.

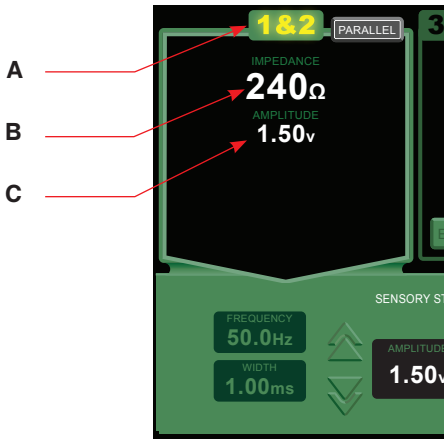


Figure 16 Typical Parallel Bipolar Stimulation Screen - ACTIVE

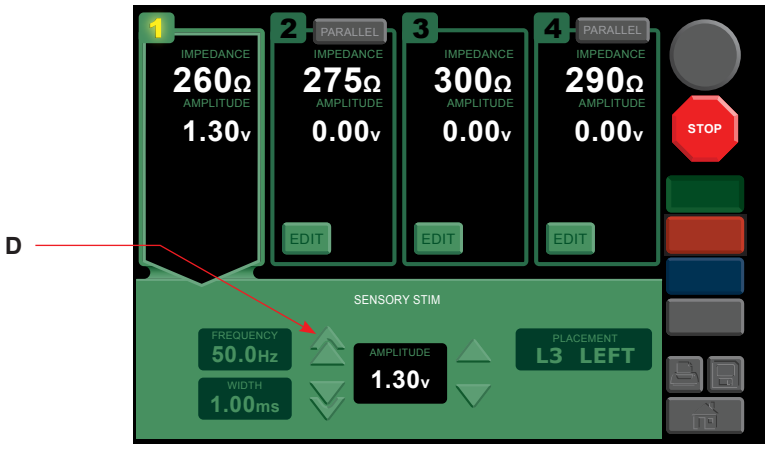


Figure 17 Typical Stimulation Screen - ACTIVE

A	**Merged Procedure Tabs** Indicates two electrodes (1,2) or (3,4) are combined to operate in a parallel bipolar mode.
B	**IMPEDANCE Procedure Tab Value** • This value, displayed in ohms [0-2000 Ω], is continuously monitored and represents tissue impedance measured by the electrode(s). • In stimulation screens, the measurement of tissue impedance is provided to distinguish between tissue types. Because different tissue types have different conductivity, a distinction can be made between tissue types, for example, between nerve tissue and muscle tissue. • If no electrodes are connected, the IMPEDANCE tab value will display "- - -." If an electrode is connected to any port, but the value exceeds its limit, the value displayed will be "HIGH" for all tabs. • Stimulation cannot be conducted if impedance is outside the range of 35 to 1800 Ω impedance.

C	**AMPLITUDE Procedure Tab Value** This value, displayed in volts, represents the amplitude of the applied stimulation energy.
D	**AMPLITUDE FAST/SLOW Arrow Button(s)/Window** Once the START button is touched, the amplitude value may be adjusted by touching the up and down arrows to increase or decrease the value, respectively. A FAST arrow (double arrow) will allow 0.1 value changes. A SLOW arrow (single arrow) will allow 0.01 value changes. To make rapid changes, touch and hold the desired button. The selected value is displayed in the window.

Instructions (continued)

To EDIT RF Output Settings:

After the sensory and motor stimulation procedures have been accomplished, ensure the RF output setting values have been adjusted as required. From the RF output screen, touch the EDIT button on the procedure tab to select and edit the setting values (see figures 18, 19, 20, and 21).

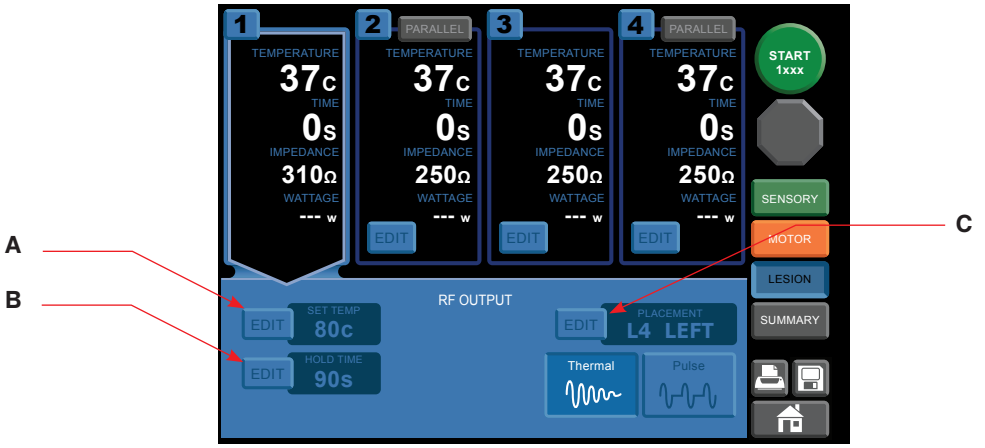


Figure 18 RF Output Screen in THERMAL Mode - INACTIVE

Figure 19 Typical Keypad Dashboard [HOLD TIME]

A	**EDIT SET TEMP Button/Window** Touch to enter a specific set temperature.
B	**EDIT HOLD TIME Button/Window** Touch to enter a specific hold time.
C	**EDIT PLACEMENT Button/Window** Touch to enter the electrode placement information. See *To Choose A Placement Region* section.
D	**Keypad Buttons** Touch to enter a specific value. The value appears in the NEW VALUE window.
E	**NEW VALUE Window** Displays the value entered using the keypad buttons.
F	**RANGE Area** View the acceptable range of values that may be entered for this setting.

To EDIT RF Output Settings (continued)

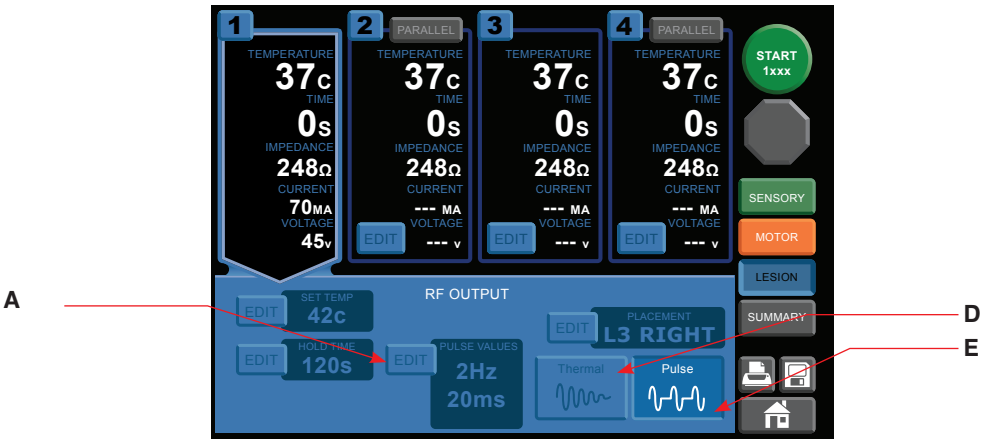


Figure 20 RF Output Screen in PULSE Mode - INACTIVE

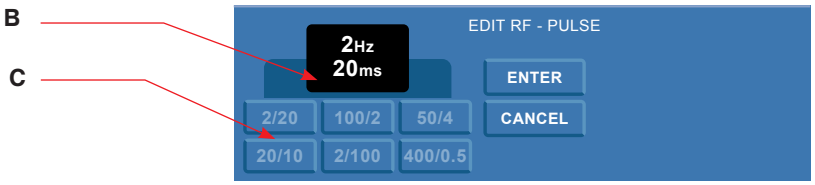


Figure 21 RF Output PULSE Preset Dashboard

WARNING: When attempting PULSE RF lesion creation, inadvertent selection of the THERMAL RF button may result in undesired tissue damage and result in patient injury.

NOTE: THERMAL and PULSE modes of operation may be performed at the same time in separate procedure tabs.

A	**EDIT PULSE VALUES Button/Window** Available in PULSE mode only, touch to select a preset value and a PULSE CONTROL option. The selected value appears in the window.
B	**NEW VALUE Window** Displays the selected new value.
C	**Preset Value Buttons** Touch to select a preset setting.
D	**THERMAL Button** Touch the THERMAL RF mode button to select the THERMAL RF mode of operation. This mode of operation provides high dose RF energy to elevate the temperature of the target tissue in a controlled manner.
E	**PULSE Button** Touch the PULSE RF mode button to select the PULSE RF mode of operation. This mode of operation provides pulsed or bursts of RF energy to stimulate the target tissue with a minimum temperature elevation.

Instructions (continued)

To Control RF Output

WARNINGS:

- To prevent patient burn injury, make sure the electrode is fully inserted into the cannula.
- Before creating a lesion, use the motor stimulation procedure to ensure motor nerves are not in the vicinity of the active electrode/cannula tip. Failure to comply may result in patient motor nerve destruction.
- When attempting PULSE RF lesion creation, inadvertent selection of the THERMAL RF button may result in undesired tissue damage and result in patient injury.
- DO NOT touch the metal wire of the electrode during the lesion creation process. RF energy output does not require the continuous activation of user input. Once the lesion creation process has been initiated, the RF output will remain energized until the lesion creation process terminates.
- While RF output is energized during the THERMAL lesion mode or the PULSE lesion mode, an unintended neuromuscular stimulation may occur resulting in an inadvertent muscle contraction.
- If the generator experiences an operational failure, an unintended increase in RF energy output may occur.

NOTE: To control RF energy output, see the appropriate procedure including *To Start Single Electrode(s) (separately or staggered)* section, *To Start Multiple Electrodes (concurrently)* section, and *To Perform a Parallel Bipolar Procedure* section.

To Start Single Electrode(s) - separately or staggered:

1. Ensure the RF energy output setting values have been adjusted as required. See *To Edit RF Output Settings* section.
2. Verify the actual temperature value displayed is approximately 37°C (body temperature) and the impedance value displayed is within a normal range for the procedure. Ensure the electrode identifier number corresponds to the desired tagged electrode.
3. Touch and confirm the START button to apply RF energy output (see figure 22). The electrode identifier number will flash and an audible beep will be heard to indicate the application of RF energy output (see figures 23 and 24).
4. If RF energy output must be removed before the end of the HOLD TIME period, touch the STOP ALL button. The STOP ALL button will remove RF energy output from all active electrodes.
5. To start an additional active electrode, select the appropriate procedure tab and repeat the steps above. An additional electrode can be activated at anytime during an active procedure. To start multiple electrodes concurrently, see *To Start Multiple Electrodes (concurrently)* section.

NOTE: An additional electrode may be connected to the generator while a procedure is in progress. However, the additional electrode will not be available for set up or the application of energy until the procedure in progress is complete.

Figure 22 RF Output Screen - START CONFIRM Dashboard

A	**CONFIRMATION MESSAGE Area** View the designated port(s) information where RF energy output will be applied.
B	**START Button** Touch to confirm the application of RF energy output to the designated electrode(s).
C	**CANCEL Button** Touch to prevent the confirmation and application of RF energy output.

To Control RF Output:

To Start Single Electrode(s) - separately or staggered (continued)

Figure 23 RF Output Screen THERMAL mode - ACTIVE

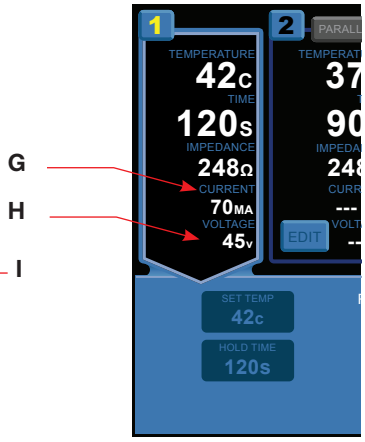


Figure 24 RF Output Screen PULSE mode - ACTIVE

A	**TEMPERATURE Tab Value** • The actual value, displayed in degrees Celsius, is continuously monitored and represents the temperature at the electrode tip. • If no electrode is connected, the tab will display “----.”
B	**TIME Tab Value** Value displayed represents the HOLD TIME value remaining in seconds.
C	**IMPEDANCE Tab Value** • The value, displayed in ohms [0-2000 Ω], is continuously monitored and represents tissue impedance measured by the electrode(s). • If no electrodes are connected, the IMPEDANCE tab value will display “- - -.” If an electrode is connected to any port, but the value exceeds its limit, the value displayed will be “HIGH” for all tabs. • A lesion cannot be created if the impedance value is outside the range of 35 to 1800 Ω.
D	**WATTAGE Tab Value** • Available in the THERMAL mode only, continuously displayed during active RF energy output and represents the approximate power output. • If no electrode is connected, output is not active, or output is less than 0.1 W, the window will display “----W”.
E	**SET TEMP Window** Indicates the SET TEMPerature value in the THERMAL or PULSE mode.
F	**HOLD TIME Window** Indicates the HOLD TIME value in the THERMAL or PULSE mode.
G	**CURRENT Tab Value** • Available in the PULSE mode only, the value displayed represents the current in milliamps. • If no electrode is connected or output is not active, the window will display “----mA”.
H	**VOLTAGE Tab Value** • Available in the PULSE mode only, the value displayed represents the voltage in volts. • If no electrode is connected or output is not active, the window will display “----V”.
I	**STOP ALL Button** Touch to remove the application of RF energy output from all active electrodes.

Instructions

To Control RF Output (continued)

To Start Multiple Electrodes - concurrently

NOTES:

- When multiple electrodes are applying RF energy output, each electrode is controlled and monitored individually.
- If a non-system error occurs with an electrode, only that electrode will stop applying RF energy. The other selected and locked electrodes will continue to apply RF energy.
- For thermal procedures, the HOLD TIME value will begin to count down independently for each electrode as the electrode tip reaches the set temperature value. Therefore, each procedure may end at a different time.
- If concurrent electrode use is desired, select and lock all the electrode identifier numbers that are required, then touch the START button.

1. Adjust the RF energy output setting values as required for each electrode. See *To Edit RF Output Settings* section.
2. Verify the actual temperature value displayed is approximately 37˚ C (body temperature) and the impedance value displayed is within a normal range for the procedure.
3. Touch the electrode identifier number(s) to select and lock the desired electrode(s) before use. The number(s) will remain depressed to indicate they are selected, locked and ready to apply RF energy output (see figure 25).
4. Touch the START button. A START confirmation dashboard will display the number of electrodes that will apply RF energy output. Touch the START button on the dashboard to confirm the application of RF energy output.
5. The electrode identifier number(s) of each active electrode(s) will flash and an audible beep will occur to indicate the application of RF energy output.
6. If RF energy output must be stopped before the end of the HOLD TIME period, touch the STOP ALL button. The STOP ALL button will remove RF energy output from all active electrodes. To restart the procedure, each of the electrode identifier numbers used previously must be selected and locked again before touching the START button to apply RF energy output.

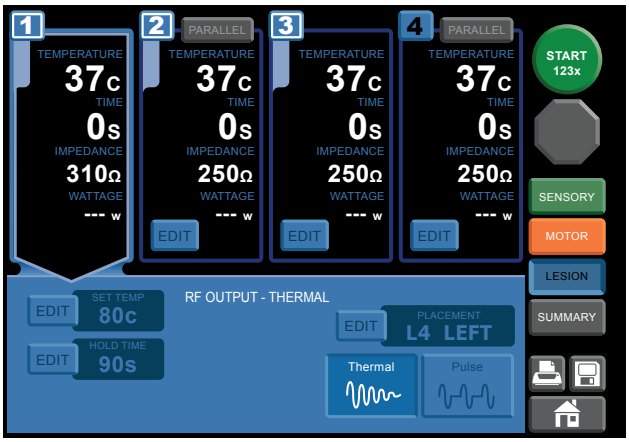


Figure 25 RF Output Screen THERMAL mode - INACTIVE - SELECTED AND LOCKED ELECTRODES 1, 2, and 3

To Control RF Output (continued)

To Perform a Parallel Bipolar Procedure

NOTES:

- The RF output PULSE screens associated with the parallel bipolar procedure have corresponding sensory and motor stimulation screens that are identical in appearance and functionality to the previously described sensory and motor stimulation screens.
- The generator is designed to control temperature based on the electrode that reaches the highest temperature. Due to impedance variations found in different types of tissue, one of the electrodes may not achieve the SET TEMPerature value.
- When performing a parallel bipolar procedure, ensure the electrode tips DO NOT touch each other. Failure to comply will result in a closed RF circuit and ineffective lesion creation. See *Appendix C - Relative Lesion Sizes and Shapes* section.

1. Touch the PARALLEL button. If performing a sensory or motor stimulation procedure, this button should already be selected.
2. Observe the electrode identifier numbers merge into one procedure tab indicating the two electrodes are operating in a parallel bipolar mode (see figures 26 and 27).
3. Adjust the RF energy output setting values as required. See *To Edit RF Output Settings* section.
4. Verify the actual temperature value displayed is approximately 37°C (body temperature) and the impedance value displayed is within a normal range for the procedure.
5. Touch and confirm the START button to apply RF energy output. The electrode tab number will flash on the screen and an audible beep will be heard to indicate the application of RF energy output.
6. If the RF energy output must be stopped before the end of the HOLD TIME period, touch the STOP ALL button. The STOP ALL button will remove the RF energy output from all active electrodes.
7. To start an additional electrode, select the appropriate electrode identifier number and repeat the steps above. An additional electrode may be activated at anytime during an active procedure. To start multiple electrodes, see *To Start Multiple Electrodes (concurrently)* section.

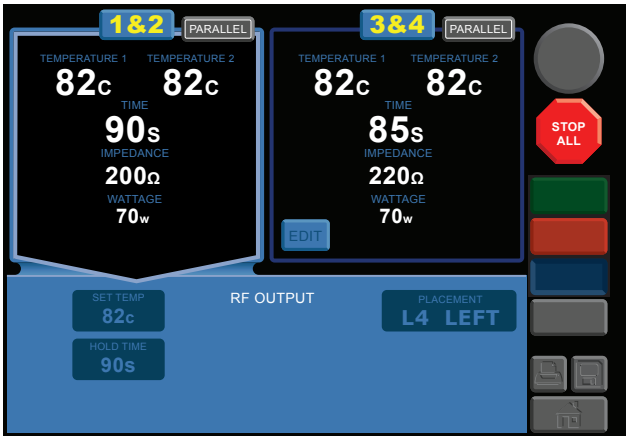


Figure 26 RF Output Screen THERMAL mode - PARALLEL BIPOLAR ACTIVE

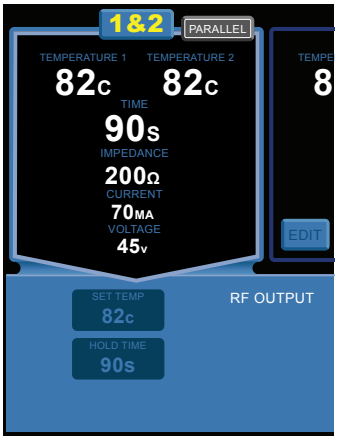


Figure 27 RF Output Screen PULSE mode - PARALLEL BIPOLAR ACTIVE

Instructions (continued)

To Choose a Placement Region

NOTE: Entering electrode placement information is not mandatory. However, if entered, the information is displayed in both the summary screen and printout.

1. Touch the EDIT placement button on the sensory, motor or lesion procedure screens to access the choose placement region dashboard.
2. Touch the CERVICAL, THORACIC, or LUMBAR/SACRUM buttons to access a specific anatomical region dashboard (see figure 28).
3. Touch the appropriate preset placement button to identify the spine location where the cannula will be placed (see figure 29). Touch the ENTER button to confirm the location. The selected placement location will be displayed in the placement location window of each procedure screen.

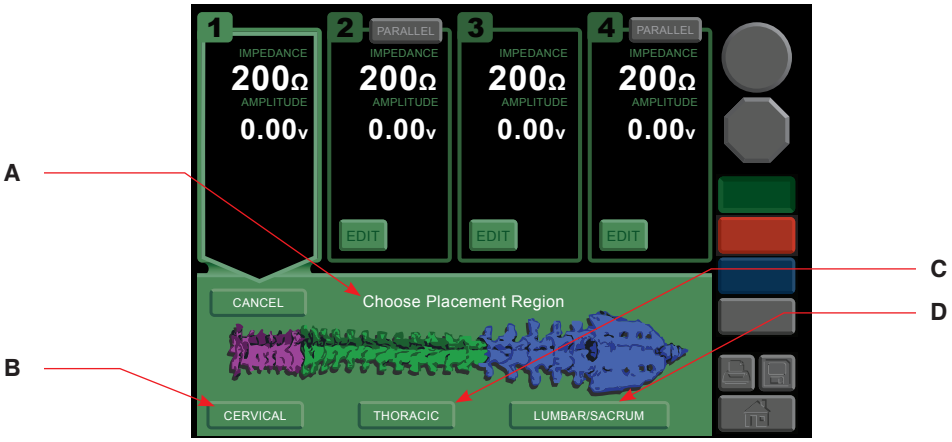


Figure 28 Choose Placement Region Dashboard

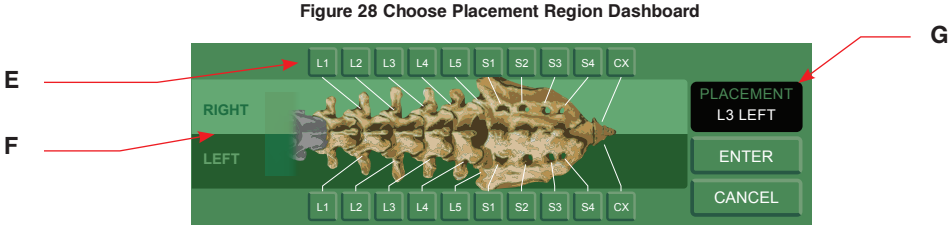


Figure 29 Typical CHOOSE PLACEMENT Dashboard [LUMBAR]

A	**CHOOSE PLACEMENT REGION Dashboard** Touch one of the anatomical region buttons to access a region dashboard.
B	**CERVICAL Button** Touch to access the cervical region dashboard.
C	**THORACIC Button** Touch to access the thoracic region dashboard.
D	**LUMBAR/SACRUM Button** Touch to access the lumbar/sacrum region dashboard.
E	**Preset Placement Buttons** Touch the appropriate button to select a preset placement location. Touch ENTER to accept the location. Buttons are labeled as follows: • C1, C2, etc., represent each cervical vertebra and its numeric position in the spine. • T1, T2, etc., represent each thoracic vertebra and its numeric position in the spine. • L1, L2, etc., represent each lumbar vertebra and its numeric position in the spine. • S1, S2, etc., represent each sacrum vertebra and its numeric position in the spine.
F	**RIGHT and LEFT Regions** Indicates the right and left side of the placement region (spine).
G	**PLACEMENT Location Window** Displays the selected placement location information.

To View a Procedure Summary:

From any procedure screen, touch the SUMMARY button to display key information related to the last completed stimulation procedure and lesion procedure (see figure 30). When you leave the procedure summary screen, you will be prompted to retain or discard the information. You also have the option to print the information. All procedure summary data will be lost permanently when power is removed from the generator. The parallel button must be selected to view parallel procedure summary information.

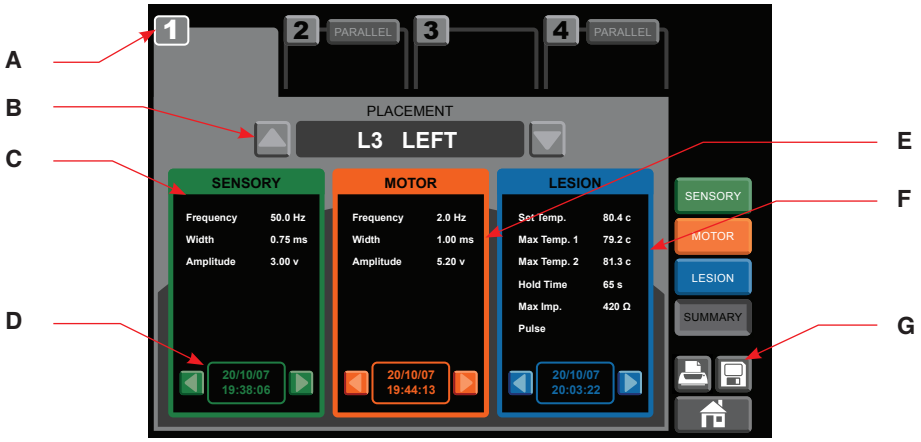


Figure 30 Procedure Summary Screen

A	**Electrode Tab** Touch to select and view the procedure summary information for a given electrode.
B	**PLACEMENT Selection Area - Up/Down Arrow Buttons** Touch to scroll through the placement information. The sensory, motor, and lesion procedure setting values associated with each placement will be displayed.
C	**SENSORY Summary Window** View sensory stimulation values collected during procedure performance. Data collection occurs after the START button is touched and continues throughout the procedure. Data is also collected if adjustments are made. Data collection ends when the procedure ends or the STOP button is touched.
D	**Date and Time Window - Left/Right Arrow Buttons** Touch to scroll through and view the date and timestamp information captured during data collection. The procedure values associated with each date/timestamp will be displayed.
E	**MOTOR Summary Window** View motor stimulation values collected during procedure performance. Data collection occurs after the START button is touched and continues throughout the procedure. Data is also collected if adjustments are made. Data collection ends when the procedure ends or the STOP button is touched.
F	**LESION Summary Window** View lesion creation values collected during procedure performance. Data collection occurs after the START button is touched and continues throughout the procedure. Data is also collected if adjustments are made. Data collection ends when the procedure ends or the STOP button is touched. Collected values include maximum values of temperature and impedance. If the PULSE mode was used, the pulse frequency and width values will also be displayed.
G	**SAVE Button** Touch to save the procedure file setting information.

Instructions (continued)

To Name (and Create) a Printout, Folder or File:

The keyboard screen may be accessed in multiple ways and serves multiple functions (see figure 31). From the Sensory, Motor, Lesion, and Procedure Summary screens, touch the PRINT button to name and print out summary information. From the Select Folder or Select File screen, touch the EDIT NAME button to change the name of an existing folder or file. From the Select Folder or Select File screen, touch the NEW FOLDER button or NEW FILE button to name and create a new folder or file.

Figure 31 Typical Keyboard Screen

A	**Title Window** Enter a printout, folder, or file name up to 25 characters in length (for example, patient name or level treated).
B	**SPACE Key** Touch to enter a space between characters.
C	**SHIFT Key** Touch to enter the & [ampersand] and - [dash] characters. The key toggles on and off when touched.
D	**Alphanumeric Keyboard** Touch to enter or modify the name of a printout, folder, or file.
E	**DELETE Key** Touch to delete the character directly to the left of the cursor.
F	**Arrow Keys** Touch the appropriate arrow key to move the cursor to the left or right. New characters will be inserted at the cursor.

To Save or Access Saved Procedure Settings

From the Procedure screens, touch the SAVE button (diskette) to save the procedure settings. From the Home screen, touch the SELECT SAVED PROCEDURE button to access a saved procedure settings file in a folder (see figure 32).

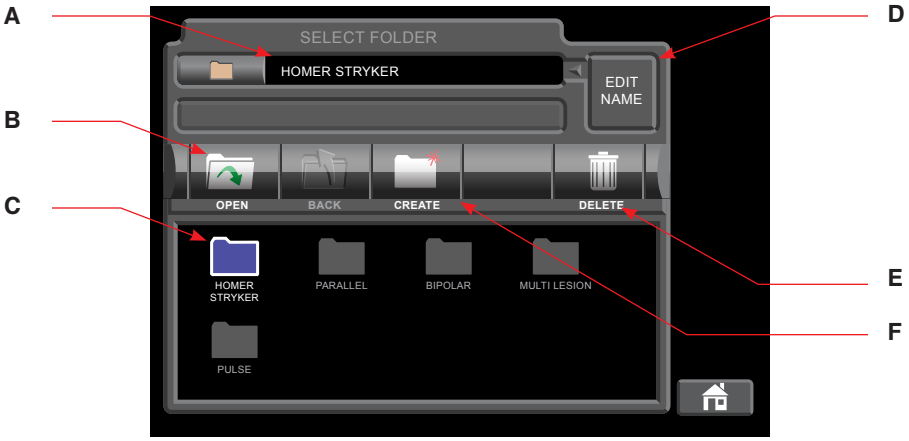


Figure 32 Select Folder Screen

A	**FOLDER Name Window** View the folder name of the selected folder.
B	**OPEN Button** Touch to open a selected folder and access the Select File screen. You may touch the selected folder again to open the folder directly.
C	**FOLDER Selection Window** View all the available folders. Touch the folder icon to select it. The selected folder is displayed as a blue folder icon.
D	**EDIT NAME Button** Touch to access a keyboard screen to change the name of a selected folder.
E	**DELETE Button** Touch to delete a selected folder. A pop up alert window will ask for confirmation. Touch the YES or NO button.
F	**CREATE Button** Touch to access a keyboard screen to enter and create a new folder [up to 5 folders]. The newly created folder will appear in the FOLDER Selection Window.

Instructions

To Save or Access Saved Procedure Settings (continued)

From the Select Folder screen, touch the OPEN button to access the Select File screen (see figure 33).

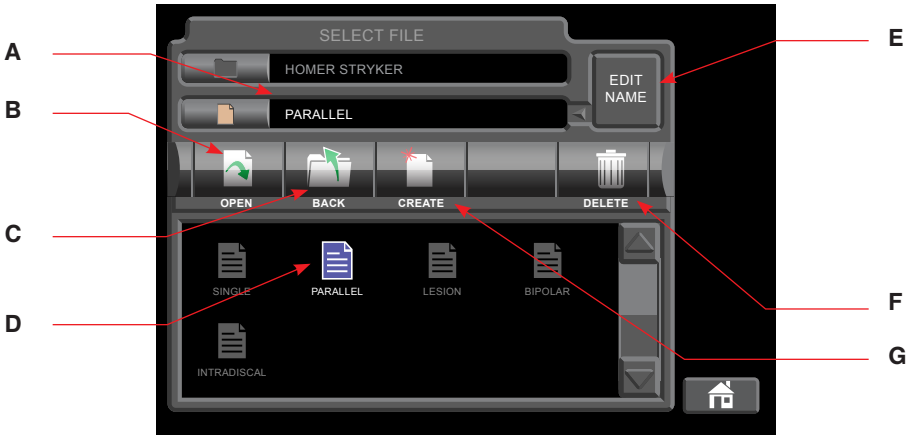


Figure 33 Select File Screen

A	**FILE Name Window** View the file name of the selected file.
B	**OPEN Button** Touch to access the File Setting screen and open a selected file. You may touch the selected file again to open it directly.
C	**BACK Button** Touch to return to the Select Folder screen.
D	**FILE Selection Window** View all the available files. Touch the file icon to select it. The selected file is displayed as a blue file icon.
E	**EDIT NAME Button** Touch to open a keyboard screen to change the name of a selected file.
F	**DELETE Button** Touch to delete a selected file. A pop up alert window will ask for confirmation. Touch the YES or NO button.
G	**CREATE Button** Touch to access a keyboard screen to enter and create a new procedure file [up to 5 files]. The newly created file will appear in the FILE Selection Window.

To Create or Access File Settings

From the Select File screen, touch the OPEN button to access the File Settings screen (see figure 34).

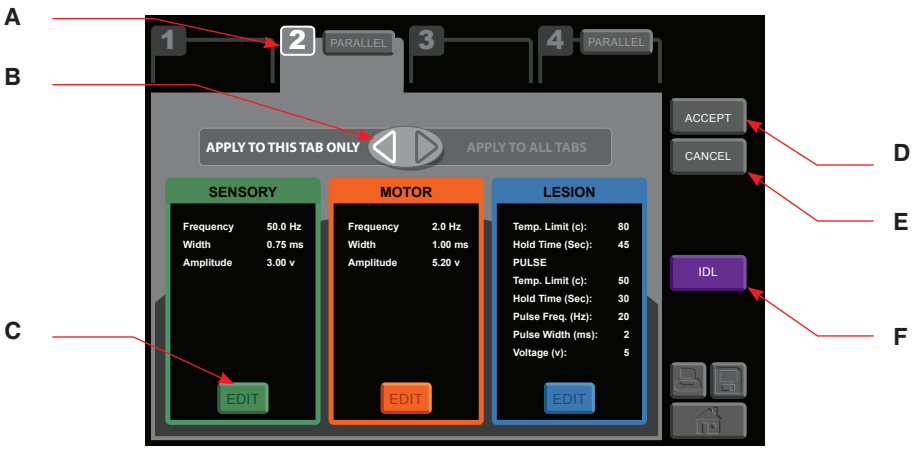


Figure 34 File Settings Screen

A	**Electrode Identifier Number** Touch to view the file setting values of a selected procedure tab.
B	**Procedure Tab Selection Button** Touch to select all procedure tabs or individual tabs when modifying the file setting values. If APPLY TO ALL TABS is selected, the values for the current selected tab will be applied to the other three tabs. If APPLY TO THIS TAB ONLY is selected, each tab may be edited individually.
C	**EDIT Setting Value Button(s)** Touch to edit the setting values for the sensory, motor or lesion procedures.
D	**ACCEPT Button** Touch to accept the file setting values displayed.
E	**CANCEL Button** Touch to cancel any changes made to the file setting values.
F	**Intradiscal Lesion (IDL) Button** The intradiscal adapter cable and catheter procedure are no longer available.

To Edit File Settings

From the File Setting screen, touch the EDIT button to access an Edit File Settings screen (see figure 35). See *To EDIT Sensory or Motor Stimulation Settings* section or *To Edit RF Output Settings* section to edit file setting values. To save changes and return to the File Settings screen, touch the SUMMARY button.

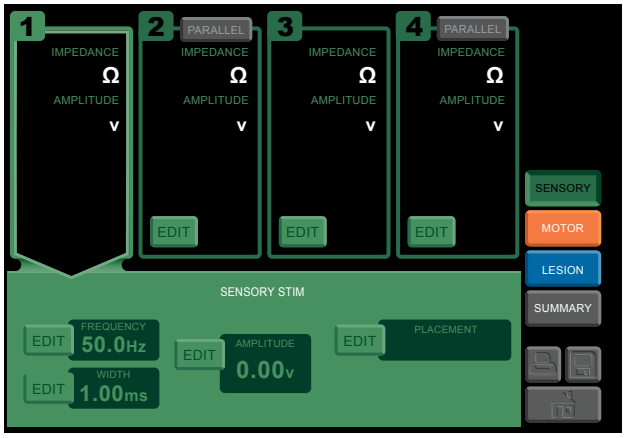


Figure 35 Typical Edit File Settings Screen

Instructions (continued)

To Change System Settings: Registration

From the Home screen, touch the SYSTEM SETTINGS button to modify system and procedure default setting values (see figure 36).

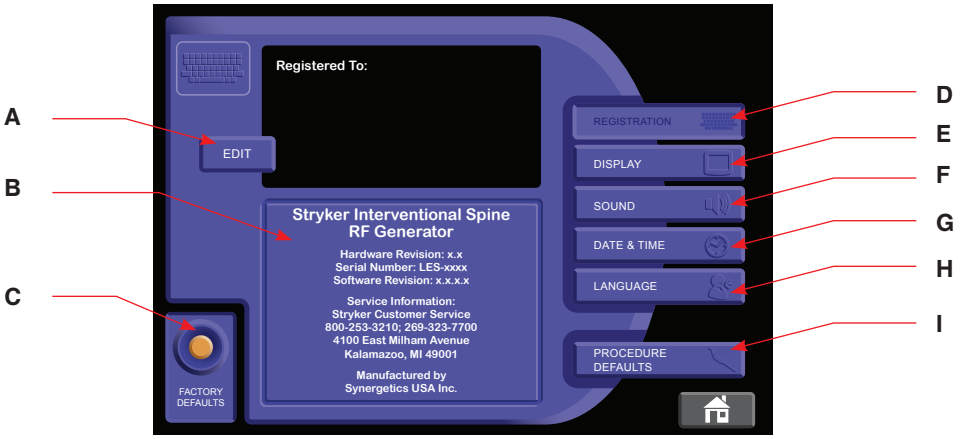


Figure 36 System Settings Screen [REGISTRATION]

A	**EDIT Button/Registered To: Window** Touch to access a keyboard screen to enter or edit the registration information. The window displays the registration information.
B	**Information Window** Displays generator information related to software, hardware, and service.
C	**FACTORY DEFAULTS Button** Touch to remove all user-created files and folders in the file management system and reset the generator system defaults to the original factory default setting values.
D	**REGISTRATION Button** Touch to access the Registration screen.
E	**DISPLAY Button** Touch to access the Display Settings screen.
F	**SOUND Button** Touch to access the Sound Settings screen.
G	**DATE & TIME Button** Touch to access the Date and Time screen.
H	**LANGUAGE Button** Touch to access the Language Settings screen.
I	**PROCEDURE DEFAULTS Button** Touch to access the Procedure Defaults screen.

To Change System Settings: Display Settings

From the System Settings screen, touch the DISPLAY button to access the Display Settings screen (see figure 37).

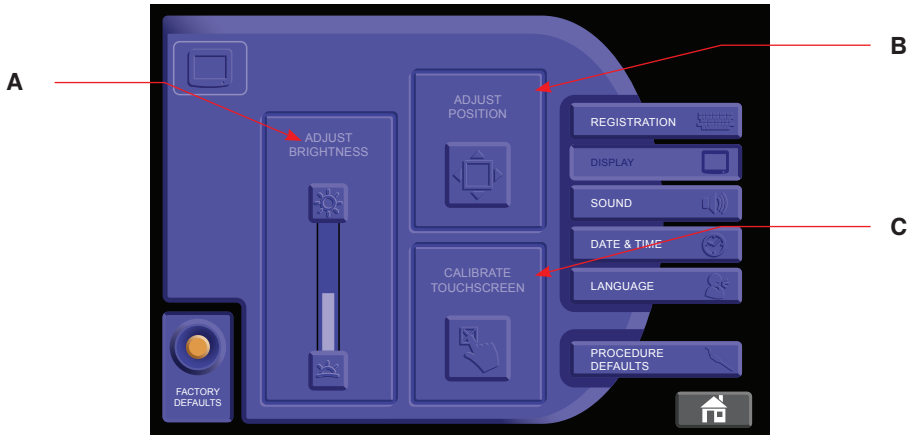
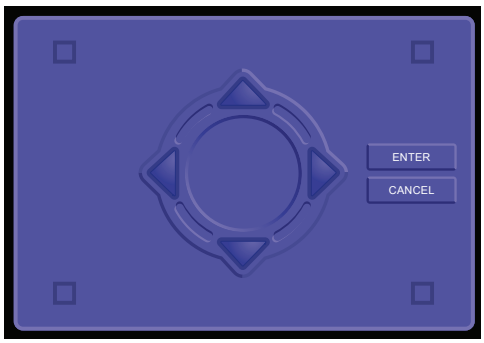
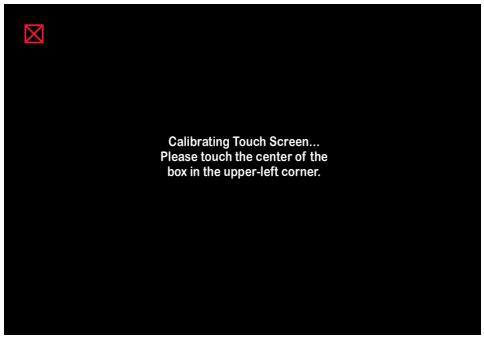


Figure 37 Display Settings Screen

A	**ADJUST BRIGHTNESS Increase/Decrease Buttons** Touch to increase or decrease the display brightness.
B	**ADJUST POSITION Button** Touch to access the Display Position screen. Touch the arrow buttons to adjust the horizontal and vertical position of the display. 
C	**CALIBRATE TOUCHSCREEN Button** Touch to access the touch screen calibration screen. Touch the center of the red box once at each unique location as it moves around the screen. DO NOT touch the red box more than once at any location. Follow the instructions on the screen to assist in the calibration process. **NOTE:** DO NOT touch any part of the screen except the center of the red box during calibration. 

Instructions (continued)

To Change System Settings: Sound Settings

From the System Settings screen, touch the SOUND button to access the Sound Settings screen (see figure 38).

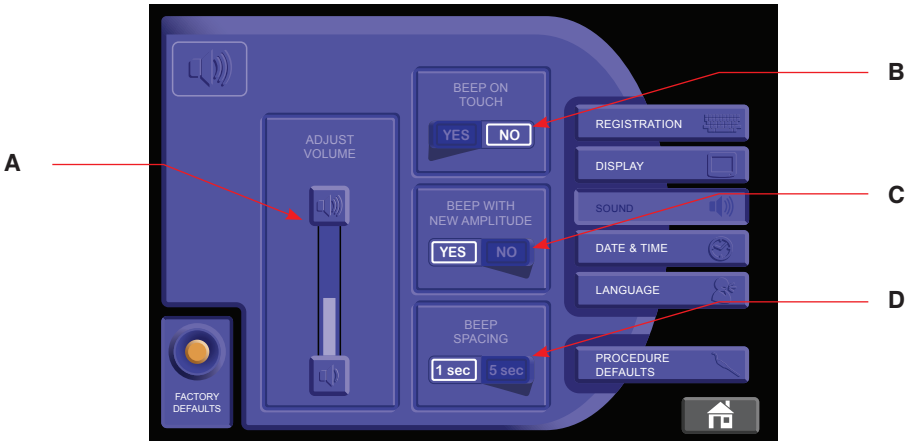


Figure 38 Sound Settings Screen

A	**ADJUST VOLUME Buttons** Touch the buttons to increase or decrease the speaker volume.
B	**BEEP ON TOUCH Switch** Touch to activate [YES] or deactivate [NO] a beep sound when any button (except the amplitude adjustment) is touched on the screen.
C	**BEEP WITH NEW AMPLITUDE Switch** Touch to activate [YES] or deactivate [NO] a beep sound when the arrow buttons are touched during amplitude adjustment on the active sensory or motor stimulation screens. The arrow buttons will respond to an initial touch only. The sound will not continue if an arrow button is touched and held.
D	**BEEP SPACING Switch** Touch to select a [1 SECond] beep spacing or a [5 SECond] beep spacing during RF energy output. **NOTE:** For safety reasons, the beep sound cannot be turned off.

To Change System Settings: Date and Time Settings

From the System Setting screen, touch the DATE and TIME button to access the Date and Time screen. (see figure 39).

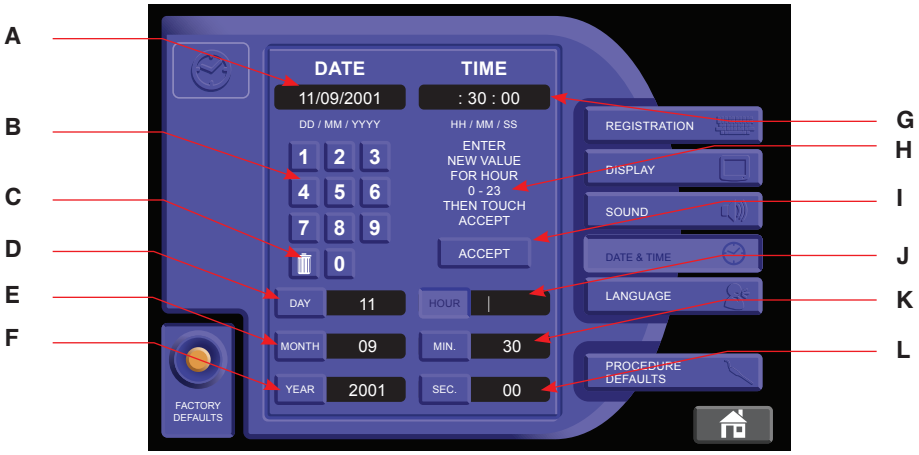


Figure 39 Date and Time Screen

A	**DATE Window** View the date (day/month/year) currently applied.
B	**Keypad Buttons** Touch to enter new values. Touch ACCEPT button to apply the new values.
C	**Delete Button/Backspace Button** Touch to delete the character directly to the left of the cursor. Touch to move the cursor left.
D	**DAY Button/Window** Touch to enter a new day value using the keypad buttons. The new value will appear in the window.
E	**MONTH Button/Window** Touch to enter a new month value using the keypad buttons. The new value will appear in the window.
F	**YEAR Button/Window** Touch to enter a new year value using the keypad buttons. The new value will appear in the window.
G	**TIME Window** View the time (hour:minutes:seconds) currently applied.
H	**RANGE Window** View the acceptable range for a new value.
I	**ACCEPT Button** Touch to apply a new value entered using the keypad buttons. The new value will appear in the DATE and/or TIME window. If you touch ACCEPT with no date or time information in a window, no date or time information will appear on the summary printout. If you fail to touch ACCEPT after entering a new value, the new value will not be saved.
J	**HOUR Button/Window** Touch to enter a new hour value using the keypad buttons. The new value will appear in the window.
K	**MINute Button/Window** Touch to enter a new minute value using the keypad buttons. The new value will appear in the window.
L	**SECond Button/Window** Touch to enter a new second value using the keypad buttons. The new value will appear in the window.

Instructions (continued)

To Change System Settings: Language Settings

From the System Settings screen, touch the LANGUAGE button to access the Language Settings screen (see figure 40). In the future, the screen language may be changed to one of several languages.

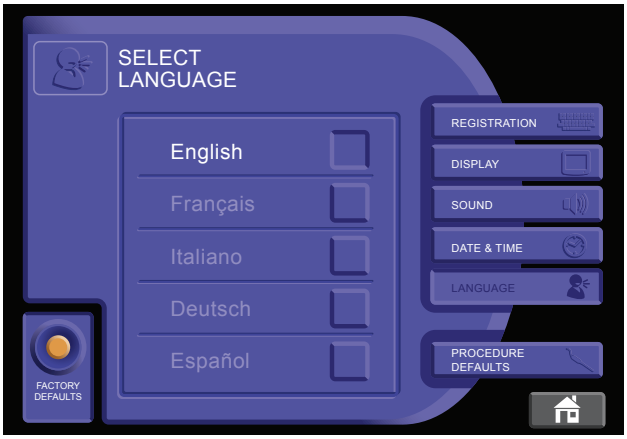


Figure 40 Language Settings Screen

To Change System Settings: Procedure Default Settings

From the System Settings screen, touch the PROCEDURE DEFAULT button to access the Set Procedure Default screen (see figure 41). See *Appendix F - Factory Default Values* section.

To Edit Procedure Default Settings

From the Set Procedure Default screen, touch the EDIT button to access an Edit Procedure Default Settings screen (see figure 42). See *To EDIT Sensory or Motor Stimulation Settings* section or *To Edit RF Output Settings* section to edit the procedure default setting values. To return to the Set Procedure Default screen, touch the SUMMARY button.

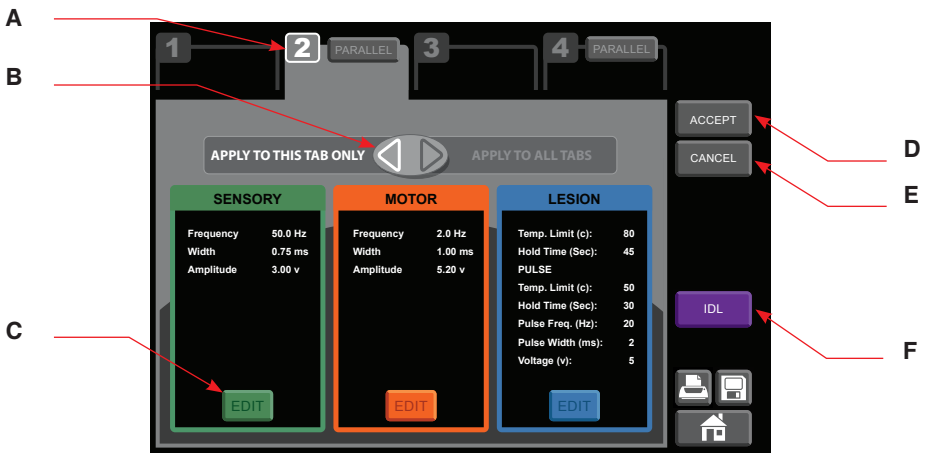


Figure 41 Set Procedure Default Screen

A	**Electrode Identifier Number** Touch to view the procedure default setting values for a specific procedure tab selection.
B	**Procedure Tab Selection Button** Touch to select all procedure tabs or individual tabs when modifying default setting values. If APPLY TO ALL TABS is selected, the values for the current selected tab will be applied to the other three tabs. If APPLY TO THIS TAB ONLY is selected, each tab may be edited individually.
C	**EDIT Settings Buttons** Touch to edit the setting values for the sensory, motor or lesion procedures.
D	**ACCEPT Button** Touch to accept changes to the procedure default setting values.
E	**CANCEL Button** Touch to cancel any changes made to the procedure default setting values.
F	**IDL Button** The intradiscal adapter cable and catheter procedure are no longer available.

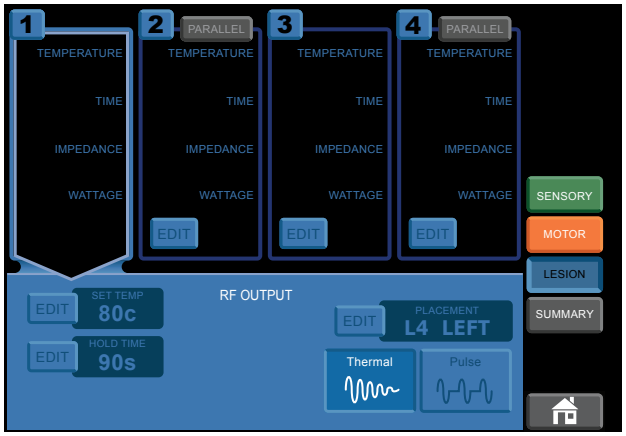


Figure 42 Typical Edit Procedure Default Settings Screen

Inspection and Testing

See the *IVS Care Instructions*.

NOTE: Maintenance documentation for this equipment is available upon request to Stryker-authorized service personnel only.

To Perform Check-in Procedure (optional)

Perform these procedures to check the accuracy of the generator's displayed values including temperature, impedance and power output. Perform these procedures in addition to any existing facility check-in protocol.

Storage and Handling

CAUTION: ALWAYS store the equipment within the specified environmental condition values throughout its useful life. See the *Specifications* section.

To ensure the longevity, performance and safety of this equipment, use of the original packaging material is recommended when storing or transporting this equipment.

GENERAL EQUIPMENT:	• Stryker RF MultiGen (generator) • MultiGen cable • Ground pad cable (monopolar return electrode cable) • Ground pad (neutral electrode) • Any size electrode • Cannula (same length as electrode, any size active tip)		
GENERAL SET-UP:	1. Connect the ground pad cable and electrode to the generator. 2. Turn the power on. 3. Remove the stylet from the cannula and place the electrode in the cannula.		
TYPE CHECK	**EQUIPMENT**	**PROCEDURE**	**RESULT**
TEMPERATURE:	• Calibrated Temperature Measurement Device • Warm Water, 37.0 ˚C to 47.0 ˚C [98.6 ˚F to 116.6 ˚F]. • Hot Water, 85.0 ˚C to 95.0 ˚C [185.0 to 203.0 ˚F].	1. Place the tip of the cannula/electrode and the calibrated temperature measurement device in the warm water. 2. Record the temperature of the tip of the cannula/electrode and the calibrated temperature measurement device. 3. Place the tip of the cannula/electrode and the calibrated temperature measurement device in the hot water. 4. Record the temperature of the tip of the cannula/electrode and the calibrated temperature measurement device. 5. Repeat the procedure for all four procedure tabs (two ports).	The temperature value displayed on the generator and the temperature value of the calibrated temperature measurement device should be within +4 ˚C/-2 ˚C from 37.0 ˚C to 95.0 ˚C.
IMPEDANCE:	500 Ohm resistors (1%)	1. Ensure the generator is in stimulation mode (either sensory or motor). 2. Carefully connect one side of the resistor to the exposed tip of the cannula/electrode. 3. Lift the white tab on the blue ground pad clamp. 4. Place the other side of the resistor across both metal pads in the ground pad clamp. 5. Return the white tab to the “closed” position to secure the connection. 6. Repeat the procedure for all four procedure tabs (two ports).	The impedance value displayed on the generator should be within 10% of the resistor value.
POWER OUTPUT:	• Gauze • Saline	1. Remove the clear plastic from the ground pad. 2. Place the metal tab of the ground pad in the slot of the blue ground pad clamp and secure the metal tab by lowering the white tab. 3. Moisten the gauze with saline and place the gauze on the sticky side of the ground pad. 4. Place the electrode/cannula in the gauze. 5. Navigate to the lesion (RF output) screen on the generator. 6. Set the temperature for 80 ˚C for 10 seconds on procedure tab 1. 7. Press the START button to apply RF energy output.	The power output value should not exceed 50 watts.

Cleaning

See the *Interventional Spine (IVS) Care Instructions*.

Troubleshooting

WARNING: DO NOT service this equipment. If you require service, contact your Stryker sales representative or call Stryker customer service. Outside the US, contact your nearest Stryker subsidiary.

PROBLEM	CAUSE	ACTION
The generator does not power up.	The generator is either not connected to facility power or the power cord plugs are not seated properly.	Make sure the generator is connected to a hospital-grade, facility power receptacle with protective earth. Make sure the power cord plugs are seated properly. See the *To Perform Initial Setup* section.
	The inlet fuses are blown.	Replace the fuses with the same type and rating. See the *Specifications* section and the *To Replace the Fuses* section.
	Electrical power is not present at the hospital-grade, facility power receptacle.	Make sure electrical power is present at the hospital-grade, facility power receptacle. If power is present and the generator still does not power up, return the generator to Stryker for repair.
Unintended button activation is experienced.	Screen is touched in two places simultaneously.	Touch the screen button in one place only.
Button does not activate when touched or is activated when not touched.	Touch screen requires calibration.	Perform touch screen calibration. See *To Change System Settings: Display Settings* section.
	Finger slid onto or off of button.	Touch the button directly. DO NOT slide onto or off of any button.
	Light button touch.	Firmly touch the button.
Temperature reading appears incorrect.	Components have not cooled down from sterilization.	After sterilization, allow components to cool to room temperature for at least ten minutes before use.
Sporadic electrical interference is experienced.	Electrical noise is present.	Turn off all electrical equipment not in use in the operating room.
		Relocate electrical equipment or electrode to maximize the distance between equipment; increase spatial distance.
		Plug the generator and other operating room equipment into different outlets (circuits).
The system impedance is too high. The instrument may be damaged.	The electrode/MultiGen cable connections is/are not secure.	Ensure all connections are secure.
	The electrode is not fully inserted into the cannula.	Ensure the electrode is fully inserted into the cannula.
	The ground pad cable connection is not secure. The ground pad placement is not secure.	Ensure the ground pad cable connection and/or the ground pad placement is secure.
	The cannula placement is not correct.	Ensure the cannula placement is correct and/or the ground pad placement is secure.
	The bipolar/monopolar mode is selected incorrectly.	Touch the PARALLEL button to select the correct mode of operation.
	The electrode, MultiGen cable, or ground pad cable is/are damaged.	Replace the electrode/MultiGen cable/ground pad cable.
		If the error persists, contact Stryker customer service.
The system impedance is too low. The instrument may be damaged.	The electrode placement is not correct.	Ensure the electrode does not touch a metal implant or the ground pad.
	The electrode placement is operating in a parallel mode.	Ensure the two electrode tips are not touching each other or a metal implant.
		If the error persists, contact Stryker customer service.
The temperature is not rising at the expected rate. The instrument may be damaged.	The electrode thermocouple is shorted.	If the temperature reading is below 36.6˚ C when the electrode is inserted in the body and/or the temperature reading is not rising when the power output is displayed as a positive value, replace the electrode.
	The electrode is not fully inserted into the cannula.	Ensure the electrode is fully inserted into the cannula.
	The patient and/or electrode and cannula are moving during the procedure.	Ensure the patient and/or electrode and cannula are not moving during the procedure.
	The electrode placement is not correct.	Ensure the active tip of the electrode is surrounded by tissue and the tip is not in a blood vessel or bone.
	The electrode or MultiGen cable is/are damaged.	Replace the electrode and/or MultiGen cable.
		If the error persists, contact Stryker customer service.

Troubleshooting (continued)

PROBLEM	CAUSE	ACTION
The temperature limit has been exceeded. The instrument may be damaged.	The electrode is not fully inserted into the cannula.	Ensure the electrode is fully inserted into the cannula.
	The patient and/or electrode and cannula are moving during the procedure.	Ensure the patient and/or electrode and cannula are not moving during the procedure.
	The electrode placement is not correct.	Ensure the active tip of the electrode is surrounded by tissue and the tip is not in a blood vessel or bone.
	A 18G cannula is in use and there is an accumulation of burnt tissue and/or blood between the electrode and cannula.	Use a sterilized pad to wipe off the electrode, especially if the same electrode is used to create multiple lesions during the procedure.
	The electrode or MultiGen cable is/are damaged.	Replace the electrode and/or MultiGen cable.
		If the error persists, contact Stryker customer service.
A rapid decrease in temperature has been detected. The instrument may be damaged.	The electrode is not fully inserted into the cannula.	Ensure the electrode is fully inserted into the cannula.
	The patient and/or electrode and cannula are moving during the procedure.	Ensure the patient and/or electrode and cannula are not moving during the procedure.
	The electrode placement is not correct.	Ensure the active tip of the electrode is surrounded by tissue and the tip is not in a blood vessel or bone.
	The electrode or MultiGen cable is/are damaged.	Replace the electrode and/or MultiGen cable.
		If the error persists, contact Stryker customer service.
A rapid increase in system impedance has been detected.	The electrode is not fully inserted into the cannula.	Ensure the electrode is fully inserted into the cannula.
	The electrode placement is not correct.	Ensure the active tip of the electrode is surrounded by tissue and the tip is not in a blood vessel or bone.
		If the error persists, contact Stryker customer service.

To Replace the Fuses

WARNINGS:

- ALWAYS remove main facility power from the generator before replacing fuses. Failure to comply may cause an electrical shock hazard.
- ALWAYS use the same type and rated fuse when replacing fuses. Failure to comply may cause a fire hazard. See the *Specifications* section.
- DO NOT use the generator if the fuses continue to blow. Contact your Stryker sales representative or Stryker customer service.

1. Press the ON/OFF button to remove power from the generator.
2. Disconnect the power cord from the generator and facility power.
3. Using a small flat blade screwdriver, gently pry open the cover of the fuse holder located on the back of the generator (see figure 43).
4. Remove the fuse holder from the generator.
5. Remove the two fuses from the fuse holder. Discard the fuses properly.
6. Install two new, properly rated fuses into the fuse holder. See the *Specifications* section for fuse ratings.
7. Insert the fuse holder into the generator.

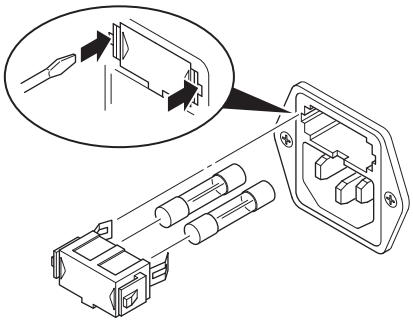


Figure 43 Fuse Replacement

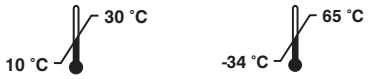
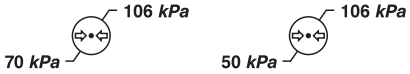
Federal Communications Commission (FCC) Statement Concerning Radio Frequency Interference

The RF MultiGen (generator) creates and uses radio frequencies and may cause interference with other medical equipment. If interference occurs, see the *Troubleshooting* section.

Specifications

Model:	REF 0406-900-000 RF MultiGen Generator
Size:	12.5 inch [317.5 mm] width, 8 inch [203.2 mm] height, 15 inch [381 mm] depth
Weight:	18 lb. [8.2 kg]
Equipment Type:	Class 1  Type BF Applied Part
Power Supply:	100 - 120 VAC ~ 50 - 60 Hz, 230 VAC ~ 50 - 60 Hz
Fuse Type and Rating	2 x 2.5 A, 250 VAC ~, (T) time-lag (slow-blow), 5 x 20 mm, IEC 127
Power Output:	50 watt maximum power into 100 ohm resistive load
Enclosure Protection:	IPX0 ordinary equipment
Protective Earth Ground:	
Mode of Operation:	Non-continuous
Duty Cycle:	999 seconds ON, 90 seconds OFF
PRODUCT SAFETY CERTIFICATION STANDARDS:	 **CSA International** C US **CANADIAN STANDARDS ASSOCIATION (CSA)** CAN/CSA-C22.2 No. 60601-1:08, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance* **AMERICAN NATIONAL STANDARDS INSTITUTE (ANSI)/ASSOCIATION FOR THE ADVANCEMENT OF MEDICAL INSTRUMENTATION (AAMI)** ANSI/AAMI ES60601-1:2005, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance*; Consolidated Reprint (2009); Amendment 2 (2010) **INTERNATIONAL ELECTROTECHNICAL COMMISSION (IEC)** IEC 60601-1:2005, Ed:3, *Medical Electrical Equipment — Part 1: General Requirements for Basic Safety and Essential Performance*; Corrigendum 1 (2006); Corrigendum 2 (2007) **EUROPEAN COMMITTEE FOR ELECTROTECHNICAL STANDARDIZATION (CENELEC)** EN 60601-1:2006, Ed:3, *Medical Electrical Equipment – Part 1: General Requirements for Basic Safety and Essential Performance;* IEC Corrigendum 1 (2006); IEC Corrigendum 2 (2007); CENELEC Corrigendum (2010); CENELEC Amendment A11 (2011)
Display Screen:	5.5 inch x 8 inch liquid crystal diode, wide 160˚ minimum viewing angle
Impedance:	
Measurement range:	0 ohm - 2000 ohms
Accuracy:	below 100 ohms ± 30 ohms; above 100 ohms ± 10%
Operating range:	35 ohms<stimulation<1800 ohms; 35 ohms<lesion<1800 ohms
Temperature:	
RF Procedure Accuracy:	+4 ˚C / -2 ˚C from 37 ˚C to 95 ˚C
Maximum Set Temperature (Thermal mode):	95 ˚C
Maximum Set Temperature (Pulse mode, 2 Hz/ 20 ms, 20 Hz/ 10 ms):	50 ˚C
Maximum Set Temperature (Pulse mode, 2 Hz/ 100 ms):	60 ˚C
Maximum Set Temperature (Pulse mode, unless specified otherwise):	80 ˚C

Specifications (continued)

Lesion Time:		0 to 999 seconds; default adjustable at system and file level
RF Frequency:		
	Conventional Heat Lesion:	1 MHz, accuracy ± 10%, DualWave Waveform: aperiodic damped sinusoid (see *Appendix D - DualWave Waveform* section)
	Pulse Mode[1]:	1 MHz sine wave with selected pulse frequency and on time, accuracy ± 10%
Stimulation Frequency:		1 to 200 Hz, separate defaults for sensory and motor stimulation adjustable at system and file level
Stimulation Type:		Biphasic square wave, voltage or current regulated; no net DC
Stimulation Pulse Width:		0.1 ms<Pulse Width< 5 ms, accuracy ± 10%, separate default for sensory and motor stimulation adjustable at system and file level
Stimulation Amplitude Voltage Regulation Mode:		0-10 V peak; accuracy ± 10%, current limited to 20 mA
Volume Adjustment:		0 dBA to 65 dBA; exceptions include alarms and lesion creation indication
Printer Compatibility:		PCL3 compliant or a more current print driver
Environmental Conditions:		**Operation** / **Storage and Transportation**
	Temperature:	
	Relative Humidity:	
	Atmospheric Pressure:	

[1]Pulse mode frequency and width tolerances may vary based on the number of active electrodes and their corresponding pulse mode settings.

Guidance and manufacturer's declaration - electromagnetic emissions		
The RF MultiGen (generator) REF 0406-900-000 is intended for use in the electromagnetic environment specified below. The customer or the user of the RF MultiGen (generator) REF 0406-900-000 should assure that it is used in such an environment.		
Emissions test	**Compliance**	**Electromagnetic environment - guidance**
RF emissions CISPR 11	Group 1	The RF MultiGen (generator) REF 0406-900-000 uses RF energy only for its internal function. Therefore, its RF emissions are very low and are not likely to cause any interference in nearby electronic equipment.
RF emissions CISPR 11	Class A	The RF MultiGen (generator) REF 0406-900-000 is suitable for use in all establishments other than domestic establishments and those directly connected to the public low-voltage power supply network that supplies buildings used for domestic purposes.
Harmonic emissions IEC 61000-3-2	Class A	
Voltage fluctuations/flicker emissions IEC 61000-3-3	Complies	

Guidance and manufacturer's declaration - electromagnetic immunity			
The RF MultiGen (generator) REF 0406-900-000 is intended for use in the electromagnetic environment specified below. The customer or the user of the RF MultiGen (generator) REF 0406-900-000 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Electrostatic discharge (ESD) IEC 61000-4-2	±6 kV contact ±8 kV air	± 6 kV contact ± 8 kV air	Floors should be wood, concrete or ceramic tile. If floors are covered with synthetic material, the relative humidity should be at least 30%.
Electrical fast transient/ burst IEC 61000-4-4	±2 kV for power supply lines ±1kV for input/output lines	±2 kV for power supply lines ±1 kV for input/output lines	Mains power quality should be that of a typical commercial or hospital environment.
Surge IEC 61000-5	±1 kV line(s) to line(s) ±2 kV line(s) to earth	± 1 kV line(s) to line(s) ± 2 kV line(s) to earth	Mains power quality should be that of a typical commercial or hospital environment.
Voltage dips, short interruptions and voltage variations on power supply input lines IEC 61000-4-11	<5% U_T (>95% dip in U_T) for 0,5 cycle 40% U_T (60% dip in U_T) for 5 cycles 70% U_T (30% dip in U_T) for 25 cycles <5% U_T (>95% dip in U_T) for 5 sec	95% Reduction (10 ms) 60% Reduction (100 ms) 30% Reduction (500 ms) 95% Reduction (5 s)	Mains power quality should be that of a typical commercial or hospital environment. If the user of the RF MultiGen (generator) REF 0406-900-000 requires continued operation during power mains interruptions, it is recommended that the RF Generator be powered from an uninterruptible power supply or a battery.
Power frequency (50/60 Hz) magnetic field IEC 61000-4-8	3 A/m	3 A/m @ 50 Hz CRT 1 A/m	Power frequency magnetic fields should be at levels characteristics of a typical location in a typical commercial or hospital environment.

NOTE: U_T is the a.c. mains voltage prior to application of the test level.

Specifications (continued)

Guidance and manufacturer's declaration - electromagnetic immunity			
The RF MultiGen (generator) REF 0406-900-000 is intended for use in the electromagnetic environment specified below. The customer or the user of the RF MultiGen (generator) REF 0406-900-000 should assure that it is used in such an environment.			
Immunity test	**IEC 60601 test level**	**Compliance level**	**Electromagnetic environment - guidance**
Conducted RF IEC 61000-4-6	3 Vrms 150 kHz to 80 MHz	3 Vrms	Portable and mobile RF communications equipment should be used no closer to any part of the RF MultiGen (generator) REF 0406-900-000, including cables, than the recommended separation distance calculated from the equation applicable to the frequency of the transmitter. Recommended separation distance $d=1.67\sqrt{P}$ $d=1.67\sqrt{P}$ 80 MHz to 800 MHz $d=2.33\sqrt{P}$ 800 MHz to 2.5 GHz Where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer and *d* is the recommended separation distance in meters (m) Field strengths from fixed RF transmitters, as determined by an electromagnetic site survey, [a] should be less than the compliance level in each frequency range. [b] Interference may occur in the vicinity of equipment marked with the following symbol:
Radiated RF IEC 61000-4-3	3 V/m 80 MHz to 2.5 GHz	3 V/m	

NOTE 1: At 80 MHz and 800 MHz the higher frequency range applies.
NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

[a]Field strengths from the fixed transmitters, such as base stations for radio (cellular/cordless) telephones and land mobile radios, amateur radio, AM and FM radio broadcast and TV broadcast cannot be predicted theoretically with accuracy. To access the electromagnetic environment due to fixed RF transmitters, an electromagnetic site survey should be considered. If the measured field strength in the location in which the RF MultiGen (generator) REF 0406-900-000 is used exceeds the applicable RF compliance level above, the RF MultiGen (generator) REF 0406-900-000 should be observed to be verify normal operation. If abnormal performance is observed, additional measures may be necessary, such as re-orienting or relocating the RF MultiGen (generator) REF 0406-900-000.

[b]Over the frequency range 150 kHz to 80 MHz, field strengths should be less than 3 V/m.

Recommended separation distances between portable and mobile RF communications equipment and the RF MultiGen (generator) REF 0406-900-000			
The RF MultiGen (generator) REF 0406-900-000 is intended for use in the electromagnetic environment in which radiated RF disturbances are controlled. The customer or the user of the RF MultiGen (generator) REF 0406-900-000 can help prevent electromagnetic interference by maintaining a minimum distance between portable and mobile RF communications equipment (transmitters) and the RF MultiGen (generator) REF 0406-900-000 as recommended below, according to the maximum output power of the communications equipment.			
Rated maximum output power of transmitter W	**Separation distance according to frequency of transmitter** **m**		
	150 kHz to 80 MHz $1.2\sqrt{p}$	80 MHz to 800 MHz $1.2\sqrt{p}$	800 MHz to 2.5 GHz $2.3\sqrt{p}$
0.01	0.12	0.12	0.23
0.1	0.37	0.37	0.74
1	1.2	1.2	2.3
10	3.8	3.8	7.3
100	12	12	23

For transmitters rated at a maximum output power not listed above, the recommended separation distance *d* in meters (m) can be estimated using the equation applicable to the frequency of the transmitter, where *P* is the maximum output power rating of the transmitter in watts (W) according to the transmitter manufacturer.

NOTE 1: At 80 MHz and 800 MHz, the separation distance for the higher frequency range applies.

NOTE 2: These guidelines may not apply in all situations. Electromagnetic propagation is affected by absorption and reflection from structures, objects and people.

Disposal/Recycle

WARNINGS:

- ALWAYS follow the current local recommendations and/or regulations governing environmental protection and the risks associated with recycling or disposing of the equipment at the end of its useful life.
- ALWAYS follow the current local regulations governing biohazard waste to safely handle and dispose of sharps.
- ALWAYS decontaminate equipment exposed to infectious material before sending the equipment to a waste treatment facility.

To comply with European Community Waste Electrical and Electronic Equipment (WEEE) Directive 2002/96/EC, DO NOT dispose of this product as unsorted municipal waste. ALWAYS collect this product separately. Contact your local distributor for disposal information.

Appendix A - RF Hand Controller Instructions

Intended Use

The RF Hand Controller is designed to be used with the RF Generator REF 0406-800-000 (generator) and RF MultiGen (generator) REF 0406-900-000. The hand controller can be used by the circulating assistant or by the surgeon from within the sterile field to control the generator and select basic system functions (see figure 44).

Features and Functions

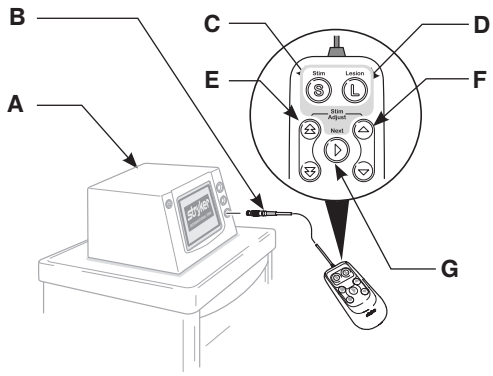


Figure 44 Hand Controller Features

A	**RF Generator** The hand controller may be used with the REF 0406-800-000 or REF 0406-900-000 generator.
B	**Controller Cable** Connect the cable to the designated port of the generator.
C	**STIM Button** Touch to select the sensory or motor stimulation mode of operation.
D	**LESION Button** Touch to select the lesion creation mode of operation.
E	**STIM ADJUST FAST Buttons** Touch to quickly increase or decrease a stimulation setting value.
F	**STIM ADJUST SLOW Buttons** Touch to slowly increase or decrease a stimulation setting value.
G	**NEXT Button** Touch to access the next screen or close a popup.

Appendix A - RF Hand Controller Instructions (continued)

NOTES:

- The RF Hand Controller allows only basic remote control of the generator. The RF Hand Controller cannot be used to create a saved file or edit procedure default setting values. Before using a RF Hand Controller during a procedure, ensure the procedure default setting values are acceptable or a saved file already exists with acceptable setting values for the procedure.
- For safety reasons, touching either the LESION or STIM button will stop RF energy output.
- Touching and holding the amplitude adjustment button during a stimulation procedure will increment or decrement the amplitude value.
- All of the RF Hand Controller buttons have multiple functionality as described below.

	SCREEN NAMES		
BUTTONS	**HOME**	**STIMULATION (INACTIVE)**	**STIMULATION (ACTIVE)**
 **LESION**	No function	No function	Press to STOP sensory or motor stimulation
 **STIM**	No function	Press to START sensory or motor stimulation	Press to STOP sensory or motor stimulation
 **NEXT**	Press to begin using the default setting values	Press to access the next screen (sensory to motor to lesion, etc.)	No function
 **INCREASE FAST**	Press to begin using the default setting values	Press to access the next procedure tab (electrode identifier 1 to electrode identifier 2 to electrode identifier 3, etc.)	Press to increase the amplitude value (0.1)
 **DECREASE FAST**	Press to begin using the default setting values	Press to access the previous procedure tab (electrode identifier 1 to electrode identifier 4 to electrode identifier 3, etc.)	Press to decrease the amplitude value (0.1)
 **INCREASE SLOW**	Press to select a saved procedure	No function	Press to increase the amplitude value (0.01)
 **DECREASE SLOW**	Press to select a saved procedure	No function	Press to decrease the amplitude value (0.01)

BUTTONS	SCREEN NAMES LESION (INACTIVE)	LESION (ACTIVE)	FILE FOLDER	POP UP
 LESION	Press to initiate lesion creation; a pop up appears to confirm the START of RF energy output	Press to STOP RF energy output	No function	No function
 STIM	No function	Press to STOP RF energy output	No function	No function
 NEXT	Press to access the next screen (sensory to motor to lesion, etc.)	No function	Press to open a selected file or folder	Press to select the OK button and close the pop up
 INCREASE FAST	Press to access the next procedure tab (electrode identifier 1 to electrode identifier 2 to electrode identifier 3, etc.)	No function	Press to access and view the next file or folder	Press to select the YES button in a pop up requiring a YES/NO response
 DECREASE FAST	Press to access the previous procedure tab (electrode identifier 1 to electrode identifier 4 to electrode identifier 3, etc.)	No function	Press to access and view the previous file or folder	Press to select YES button in a pop up requiring a YES/NO response
 INCREASE SLOW	Press to lock/unlock an electrode during a multiple electrode procedure	No function	Press to select the next file or folder	Press to select NO button in a pop up requiring a YES/NO response
 DECREASE SLOW	Press to lock/unlock an electrode during a multiple electrode procedure	No function	Press to select the previous file or folder	Press to select NO button in a pop up requiring a YES/NO response

Appendix B - Maximum Frequency and Maximum Stimulation Width Graphs

NOTES:

- The stimulation type of energy is biphasic square pulses. The width values shown are for each phase (see figures 45 and 46).
- For a fixed amplitude value, increasing the width value will pass more energy output into the patient per pulse. In general, more energy output has the effect of recruiting more nerve fibers within the cannula tip proximity and provoking a stronger response. Conversely, a reduction in the width value will reduce the patient response.
- The duty cycle of the stimulation energy is limited to 25% for safety reasons. MAX Width = 25% · 1/frequency

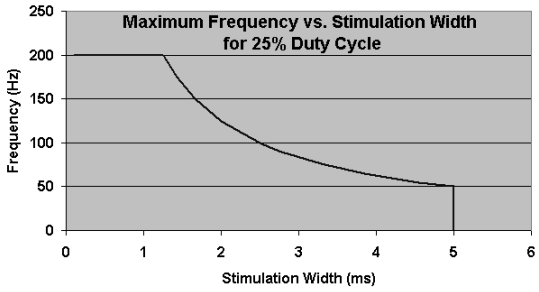


Figure 45 Maximum Frequency vs. Stimulation Width Graph

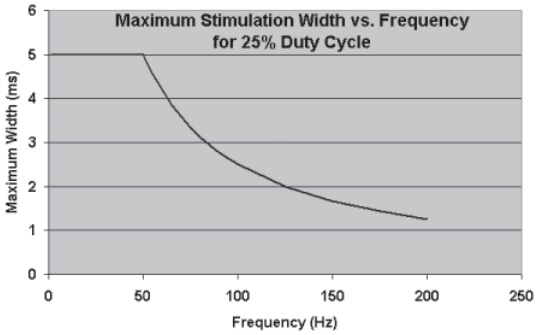


Figure 46 Maximum Stimulation Width vs. Frequency Graph

Appendix C - Relative Lesion Sizes and Shapes (parallel bipolar only)

NOTES:

- Due to the variability in distance that can arise when placing the electrodes, it is important to remember that the distance between the electrodes directly affects the relative shape and size of the resulting lesion.
- Lesion sizes can vary significantly, and depend on local tissue and thermal conductivity, proximity to 'heat sinks' such as blood vessels, and to other thermal insulation such as bone. See the lesion sizes measured in chicken tissue in figures 47, 48, 49, and 50. Lesions were created at 80 °C for 90 seconds using a 5 mm active tip 20-gauge electrode. The measurements indicated below are approximate.

2 mm

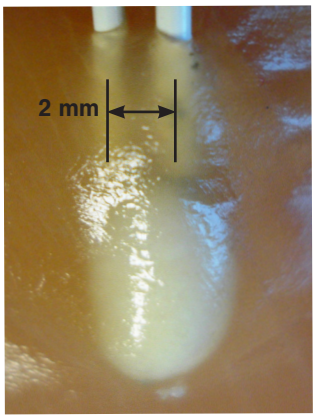


Figure 47 Contiguous Lesion 4.2 mm x 5.8 mm (width x length)

6 mm

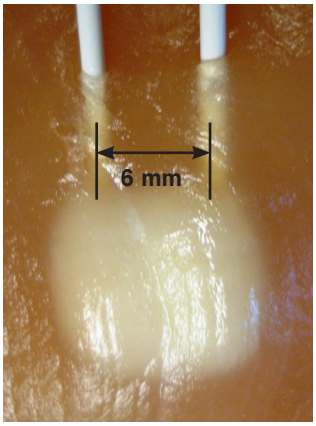


Figure 48 Contiguous Lesion 7.8 mm x 9.6 mm (width x length)

NOTES:

- At an electrode spacing of 10 mm, two independent lesions are formed, one around each electrode. The lesions tend to show a slight inclination to form toward the other electrode as shown in the 10 mm example.
- At an electrode spacing of less than 10 mm, one lesion is formed between the two electrodes. For more information, see Pino, Hoeft et al[1].

[1]Pino CA, Hoeft MA, Hofsess C, Rathmell JP (2005) Morphologic analysis of bipolar radio frequency lesions: Implications for treatment of the sacroiliac joint. Regional Anesthesia and Pain Medicine, Vol. 30, No 4 (July – August), 2005: 335–338.

10 mm

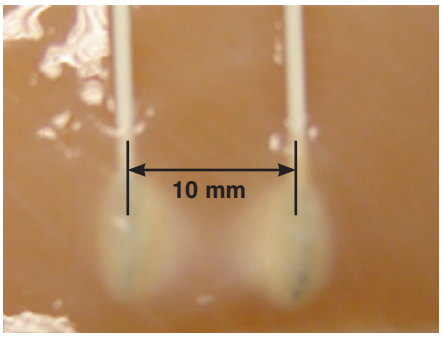


Figure 49 Non-contiguous Lesions 4.4 mm x 7.5 mm (width x length) 5.0 mm x 8.2 mm (width x length)

14 mm

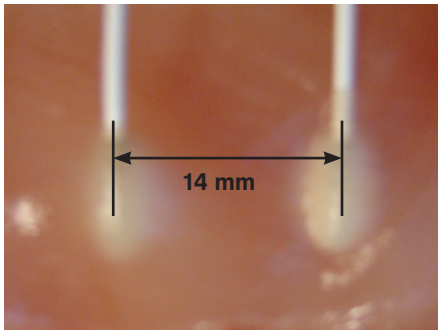


Figure 50 Non-contiguous Lesions 4.7 mm x 8.5 mm (width x length) 5.1 mm x 8.2 mm (width x length)

Appendix D - DualWave Waveform

The DualWave (THERMAL mode) waveform is an aperiodic 1 MHz damping burst of RF energy that repeats for a maximum of 125 milliseconds and is followed by 415 milliseconds of dead time. The waveform is repeated until the procedure time ends (see figure 51).

Within the six millisecond bursts, the following occurs:

1. a damped sinusoid burst is output and lasts about 10 microseconds (µs),
2. a delay of no output occurs and lasts a random amount of time,
3. steps 1. and 2. are repeated for six milliseconds.

The random length delays result in a aperiodic train of bursts.

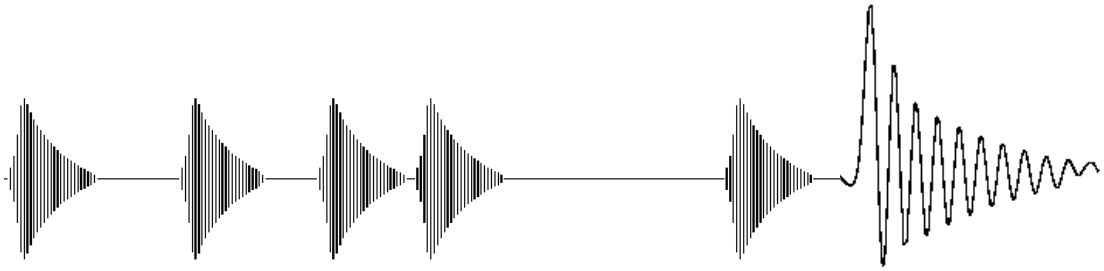


Figure 51 DualWave Waveform

Appendix E - Radio Frequency Output Plot (see figure 52)

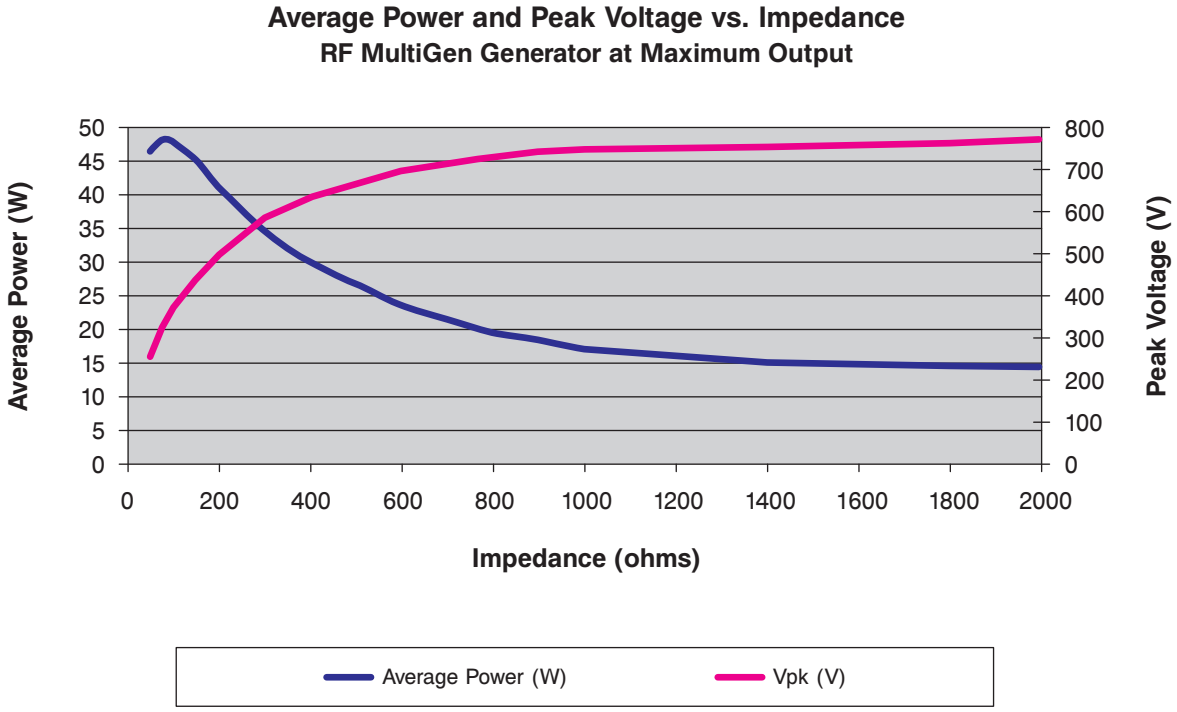


Figure 52 RF Output Plot

Appendix F - Factory Default Values

USER INTERFACE LANGUAGE	
(default)	ENGLISH

SOUND DEFAULT VALUES	
Beep On Touch Option	YES
Beep When Change Amplitude Option	NO
Output Beep Spacing Option	One second

PROCEDURE DEFAULT VALUES

Sensory Stimulation Setting Values	
Frequency	50 Hertz
Width	One millisecond
Amplitude	0.0 Volt

Motor Stimulation Setting Values	
Frequency	2 Hertz
Width	One millisecond
Amplitude	0.0 Volt

Lesion Setting Values	
Set Temperature (THERMAL mode)	37° Celsius
Hold Time (THERMAL mode)	0 second
RF Mode	THERMAL
Hold Time (PULSE Mode)	0 second
Set Temperature (PULSE Mode)	42° Celsius
Frequency (PULSE Mode)	2 Hertz
Width (PULSE Mode)	20 millisecond

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